PHD

Investigating screw insertion to optimise orthopaedic fixation (Alternative Format Thesis)

Fletcher, James

Award date:
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Department for Health

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Submitted by

James W A Fletcher

For the degree of Doctor of Philosophy

of the

University of Bath

Department for Health

April 2022

Signature of Author...

Abstract

Most people will break at least one bone in their lifetime. The individual and societal problems caused by broken bones are enormous, with a considerable reduction in quality of life and large healthcare costs. Fractures (broken bones) often require surgery to restore function such as walking, but if operations are performed such that they are at high risk of failure, it increases the risks of revision surgery, worse function and higher financial costs. Active mobile people make fewer demands of health care systems. They have better control of their co-morbidities and so keeping people mobile reduces the burden on the entire UK National Health System (NHS), especially if their function can be restored at the first operation. Furthermore, even small improvements in fracture treatments have tremendous healthcare and financial impacts to the whole population given the number of fractures happening every day.

Most operations to fix broken bones use screws to hold the broken ends together so they can heal. However, despite the incredibly frequent use of screws (tens of thousands every day in the UK alone), no previous research studies have shown how tight these screws should be when put in. There are a multitude of reasons why fixations can fail such as breakage or cutting out of the implants. Poor insertion and incorrect tightening of screws are likely to contribute to fixations failing. Indeed, these factors may explain other failure mechanisms such as screw cut out, where it might actually be overtightening of the screw in the first place that destines the fixation to failure. Failures lead to pain, poor function and increased death rates, often needing further operations to re-fix the bones. To address this and improve patient care, the objectives of this research were to find the correct tightness for screws and to develop a predictive model which is simple enough to be implemented in a surgical theatre to allow a surgeon to insert cortical screws to the optimum tightness, having established the optimum tightness for any screw hole.

By performing tests in a laboratory, a new experimental model was validated for biomechanical testing that uses bovine bones to mimic the behaviour of human bone, including low bone density conditions such as osteoporosis. Experimental simulations on the bovine model determined that the optimum tightness for screws is between 20-30% below the maximum torque that can be applied to a screw (70 to 80% of the maximum is best). Therefore, control is needed to make sure that screws are not as ‘tight as they could be’ but have a targeted amount of tightness. This previously unknown information allows surgeons to consciously tighten screws to an established amount, which is expected to improve bone healing and reducing the risk of fixation failure. The optimum tightness value for a screw changes depending on the depth of the screw hole and the density of the surrounding bone. Methods of calculating what the correct tightness is for any screw hole using adaptations to existing engineering calculations that predict the stripping torque for a homogeneous material were created. These were tested with an augmented screwdriver – one that indicated when a targeted torque had been reached (that torque being 70-80% of the calculated stripping torque) – and found dramatic improvements in screw fixation and inserter confidence. This technique was also tested on multiple biomechanical researchers and surgeons, again finding improvements.

This programme of research has proved to be novel, generating new information about how best to insert screws and has substantial potential impact to patient care given the hundreds of millions of people needing fixation in their lifetime and the billions of screws that are inserted in the UK and around the world each year. Screw insertion had been previously trivialised and thought by some to be easy and performed well. It has been shown how poorly it is often performed by reviewing previous studies into surgeon performance and by undertaking the largest study into surgical insertion techniques. This research has developed simple, clinically deliverable solutions for addressing the variation in achieved screw tightness, and the high rates of over tightening.

By looking in detail at one of the commonest surgical techniques performed – inserting a screw – for one of the commonest conditions sustained – breaking a bone – this project should improve the care for millions of patients. Hopefully surgeon understanding and education of screw insertion will improve, alongside ongoing development of augmented screwdrivers to further aid surgeons and improve patient care.

Acknowledgements

I wish to thank my supervisors Ezio, Richie and Mike for their guidance, wisdom and friendship throughout my PhD. I'm especially grateful to Ezio for his constant education, support and development of my researcher skills.

I owe a huge thanks to Professor Geoff Richards at the AO Research Institute Davos for having me as a research fellow for six months in my second year. Not only was this a tremendously fun and educational time, but it also enhanced the clinical transferability of the PhD research. My time there was made even more enjoyable through the friendship, help and corroborative opportunities provided by Peter and Boyko. Thanks to Dieter and Ivan for their help with the experimentations. Also, thanks to Juan, Lisa and especially Verena who worked really hard in getting really high-quality research produced.

Thank you to Bruno for teaching me the computational methods I needed, Ali for showing me the ropes of the labs and to Nicholas Waywell, Jack Howell, Fernando Acosta and Clare Bell for their technical expertise.

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Chapter 1 - Introduction

Screws are the most used implant in orthopaedic surgery. They have numerous functions but are mainly used to obtain stability between two or more bone sections. Sometimes relative stability of the bone sections is required to create the optimum environment for bone healing, and at other times absolute stability is targeted where they is minimal gapping of the bone ends. Screws gain purchase in a bone by generating a frictional force between the screw threads and the material between them. With a screw head preventing further linear advancement of the screw, further tightening of a screw causes more friction and compression between the screw threads and bone, increasing the force required to move the screw – thus increasing stability. Stability is important in bone healing as the implants are aiming to control the strain occurring at the fracture site, as the strain rate will dictate how quickly and successfully the bone heals. Controlling the strain rate whilst healing occurs means that the fatigue limit of the implant materials is not exceeded before bony union. If the fixation is not stable, and the strain rate not controlled, there is an increased risk of bone healing taken longer, potential so long that the endurance limit of the material is exceeded, leading to failure.

If the rotational force applied to a screw (torque) exceeds the shear limit of the bone between the threads, this bone becomes stripped. This means it is detached from the surrounding bone outside the threads of the screw, and thus the compression generated is greatly reduced. It also means that the pullout force that the screw can resist is greatly diminished and the stability of the bone sections is likely to decrease. With more instability, there is often more motion at the fracture site, that will either delay or inhibit conversion of the early constituents of bone healing from developing to the next stages in healing and remodelling.

Screws being stripped clearly means the construct will not initially work as intended. A saving factor in the fixation of fractures is that new bone could grow around the screw threads which may improve stability. However, fibrous ingrowth is seen in stripped screw holes which at a minimum will delay healing and worsen stability (Togni et al., 2011). When fixations fail, it can often be multifactorial, and hard to attribute one factor as causative. There are also sub-clinical failures, where healing and recovery take longer than predicted, potentially reducing patients' ability to mobilise whilst they are healing though ultimately achieving the same, albeit delayed, healing end point. Poor screw insertion will certainly not decrease failures, but given the difficulty in attributing failure cause, there is no clinical evidence to show the impact of poor screw insertion. However, this will be in part that no-one has looked at the impact of different screw insertion performance as such performance has not been vocalised as a priority despite how fundamental a skill it is in orthopaedic surgery and how anecdotally poorly it is often performed. Indeed, despite being so commonly used, it had always been curious to me that in my orthopaedic surgical training, minimal to no attention had been paid to teaching a standardised technique for insertion, nor had there been any assessment of my abilities to insert screws. Frequently I would experience screws being inserted where they had stripped the bone surrounding the screw by being overtightened. Screws stripping the surrounding bone seemed to be a problem, as before the operation was complete, the patient would be continuing with implanted fixation that was not doing what it was planned to – i.e. each screw inserted was done so to gain purchase in the bone to aid stability. The fact that witnessing screw stripping occurred frequently showed that it was a common problem and one that did not seem to change with experience. When asking colleagues on how tight screws should be, this would rarely be met with anything more than a qualitative response such as ‘tight enough’ or no answer at all. General screw insertion and/or an understanding of tightening are needed in many household activities such as constructing furniture or replacing lids on jars. In these instances, the maximum force (torque) that can be applied to the created construct before plastic deformation occurs is either known or predictable given the homogeneous properties of the materials being used or is so high that manually tightening would not generate enough force to reach this level. Bone, however, is heterogeneous in its material properties, and for any screw hole, there are many factors (such as the depth of the hole and the geometry of the screw threads) that will impact on the torque value beyond which plastic deformation will occur. Additionally, the torque values to strip the bone around commonly used screws can often be manually exceeded. It seemed that in general, the orthopaedic community had accepted that quantifying the torque limits for screw insertion was not either needed or possible, and that surgical skill alone would be, or would have to be, sufficient. To me, this required further evaluation as it was not apparent whether any methods for predicting the maximum tightness were known, or whether there was an optimum tightness for a screw to perform as best as intended. My concern about the community’s attitude towards screw insertion was confirmed when performing initial searches for previous experiments in this field. I was struck by the small number of tests often performed in studies, usually meaning they were underpowered – some studies even magnanimously admitted that they were underpowered for what they were looking at.

My initial steps investigating screw insertion and tightness were to review what evidence already existing for the tightness needed for screws and ways of predicting/calculating this. The literature review (Chapter 2) investigates the previous studies into screw insertion and outcomes, reporting the prior work into how tight surgeons insert screws. The literature review confirmed my initial findings that a large limitation of most previous studies into screw insertion techniques and outcomes is the underpowered nature of the biomechanical testing. One reason for this may have been the suitability of the models available for biomechanical testing. Thus, I felt that a new biomechanical model was needed to address and appropriately power future studies. In Chapter 3, I explored ways to develop and validate of a novel model of screw insertion and pullout testing in biomechanical research, using juvenile bovine bone as a surrogate of human specimens. This model had the properties required for mass screw compression and pullout testing, whilst being more available and comparable to human bone, but without the associated costs. Using this model, appropriately powered biomechanical testing could be performed to establish the optimum tightness for screws, and then this could be validated on human bone. Chapters 4 and 5 focus on finding the optimum tightness for screw fixation in bovine bone and human bone respectively. The effect of tightness was measured from screw compression and pullout strength, taken as key performance indicators of success of screw fixation. Further testing on the impact of different conditions when inserting screws was performed to establish how and why screw insertion studies should be controlled to reduce the impact of known confounders such as bone density, cortical thickness and screw diameter. Chapter 6 studied screw insertion outcomes under these and other conditions. Finally, putting these findings into practice, under very controlled conditions, Chapter 7 reports the screw insertion techniques and outcomes of 10 biomechanical researchers and 10 orthopaedically trained researchers, including using screwdriver augmentation to aid insertion. These latter chapters also explored the impact of torque feedback during insertion, and the effect of this on performance and confidence in fixation.

1.1 Note on format

This thesis is comprised of one systematic review and five research studies, presented as a collection of papers accepted in peer-reviewed international journals (i.e. ‘alternative format’). The contents of the thesis chapters and published articles associated with them are shown in Table 1-1. Each chapter is preceded by a ‘Context’ section, introducing the paper. This is followed by a statement of authorship, outlining the candidate’s contribution to the published research under the following headings: formation of ideas, design of methodology, experimental work, presentation of data in journal format. Finally, a ‘Summary’ section is included at the end of each chapter, explained how each paper relates to the overall research question.

All screws referred to in this thesis are non-locking, cortical screws, unless otherwise explicitly stated.

The references for each paper are self-contained with a full bibliography in alphabetical order at the end of the thesis.

Data access statements are given prior to each published paper that contains original experimental data.

The papers contained within this thesis have been reformatted from their published form into single column, double spaced text for the benefit of the reader.

Chapter	Published articles
Chapter 1: Introduction	
Chapter 2: literature review	Fletcher et al., *Surgical performance when inserting non-locking screws – a systematic review.* EFORT Open Reviews 2020 (5):711-721
Chapter 3: Developing a new model for in vitro biomechanical testing of screw fixation	Fletcher et al., *Juvenile bovine bone is an appropriate surrogate for normal and reduced density human bone in biomechanical testing: a validation study.* Scientific Reports 2018:8 (1), 1-9
Chapter 4: Finding the optimum screw tightness using a bovine bone model	Fletcher et al., *Non-locking screw insertion: No benefit seen if tightness exceeds 80% of the maximum torque.* Clinical Biomechanics. 2019:70, 40-45
Chapter 5: Finding the optimum tightness for non-locking screws in human bone models	Fletcher et al., *Stripping torques in human bone can be reliably predicted prior to screw insertion with optimum tightness being found between 70% and 80% of the maximum.* Bone & Joint Research 2020:9(8), 493-500
Chapter 6: Investigating the impact of different conditions on screw tightness and stripping rates	Fletcher et al., *Variations in non-locking screw insertion conditions generate unpredictable changes to achieved fixation tightness and stripping rates.* Clinical Biomechanics. 2019:70, 40-45
Chapter 7: Comparing the screw insertion outcomes of biomechanical researchers and orthopaedic surgeons	Fletcher et al., *Biomechanical researchers have lower stripping rates than orthopaedic surgeons when inserting non-locking screws.* Journal of Orthopaedic Surgery and Research 2020:16, 642
Chapter 8: Conclusions and further work	

Table 1-1 - Overview of thesis contents with reference to the research paper in each chapter

Chapter 2 - Literature review

2.1 Context

A literature review was performed looking into the previous attempts to ascertain how tight orthopaedic surgeons insert screws, to see what definition(s) of optimum tightness are used, if an optimum tightness is known and what these findings are based on. Knowing these values would greatly enhance surgical fixation as all screws could be inserted as intended. It might also mean that if screws are inserted to the optimum tightness, fewer screws might be needed, as potentially current practice might have a safety factor built in to anticipate a certain percentage of screws being stripped on insertion. If the optimum torque values were known, then my focus could shift to ways of achieving this, whereas if the optimum target was not known (and I assumed that if clear values for the optimum and maximum torques for screw holes were known, that they would have been advertised in my training), then confirming this would direct my next steps to discovering this.

2.2 Statement of authorship

This declaration concerns the article entitled:			
Fletcher et al., Surgical performance when inserting non-locking screws – a systematic review. EFORT Open Reviews 2020 (5):711-721			
Publication status (tick one)			
Draft manuscript ☐ **Submitted** ☐ **In review** ☐ **Accepted** ☐ **Published** ☑			
Publication details (reference)	Fletcher et al., Surgical performance when inserting non-locking screws – a systematic review. EFORT Open Reviews 2020 (5):711-721		
Copyright status (tick the appropriate statement)			
I hold the copyright for this material ☑	Copyright is retained by the publisher, but I have been given permission to replicate the material here ☐		
Candidate's contribution to the paper (provide details, and also indicate as a percentage)	The candidate contributed to / considerably contributed to / predominantly executed the… Formulation of ideas: 90% Design of methodology: 90% Experimental work: 100% Presentation of data in journal format: 80%		
Statement from Candidate	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature.		
Signed	[redacted]	**Date**	07/08/2021

2.3 Study 1: Surgical performance when inserting non-locking screws – a systematic review

James W A Fletcher[1, 2*], Lisa Wenzel[2,3], Verena Neumann[2], R. Geoff Richards[2], Boyko Gueorguiev[2], Harinderjit S Gill[4], Ezio Preatoni[1], Michael R. Whitehouse[5, 6]

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Abstract

- Billions of screws are inserted by surgeons each year, making them the most commonly inserted implant. When using non-locking screws, insertion technique is decided by the surgeon including how much to tighten each screw. The aims of this study were to assess, through a systematic review, the screw tightness and rate of material stripping produced by surgeons and the effect of different variables related to screw insertion.
- Twelve studies were included, with 260 surgeons inserting a total of 2,793 screws; an average of 11 screws each, although only 1,510 screws have been inserted by 145 surgeons where tightness was measured - average tightness was 78 ±10% for cortical (n=1,079) and 80 ±6% for cancellous screw insertions (n=431).
- An average of 26% of all inserted screws irreparably damaged and stripped screw holes, reducing the construct pullout strength. Furthermore, awareness of bone

stripping is very poor, meaning that screws must be considerably overtightened before a surgeon will typically detect it.

- Variation between individual surgeons' abilities to optimally insert screws was seen, with some surgeons stripping more than 90% of samples and others hardly ever. Contradictory findings were seen for the relationship between the tightness achieved and bone density.
- The optimum tightness for screws remains unknown, thus subjectively chosen screw tightness, which varies greatly, remains without an established target to generate the best possible construct for any given situation. Work is needed to establish these targets, and to develop methods to accurately and repeatably achieve them.

Keywords: Surgical technique; bone screws; screw insertion; screw tightness; stripping torque; fracture fixation, internal fixation

Background

The quality and efficacy of orthopaedic fixation relies on screw design and material, bone characteristics and surgical techniques. Traditional fixation methods using non-locking screws, to generate compression and stability, remain important despite an increased use of locking screw constructs (Egol et al., 2004b). When inserting non-locking screws, friction is generated between screw threads and the host bone to produce a shear force and counteract linear motion of the screw. This friction enables stabilisation and compression of bones and their fragments during locomotion to resist muscle and joint forces.

For non-locking screws, the force applied for tightening is subjectively chosen and controlled by the surgeon. If the torsional force applied to a screw exceeds the shear limit of the surrounding bone, the screw ‘strips’ the bone, reducing the resistance to pullout force by more than 80% (Collinge et al., 2006, Wall et al., 2010). This is an irreversible situation due to plastic deformation of the bone. These weakened constructs increase the risk of fixation failure, which doubles treatment costs and worsens patient morbidity and mortality (Broderick et al., 2013).

Attempts to quantitatively and qualitatively describe surgeons' abilities to insert screws have been performed; here we systematically review the existing work in this field. The first aim was to report the tightness of an inserted screw when expressed as a ratio (the stopping/stripping torque ratio) against the minimum stripping torque, where the stripping torque represents the upper limit of the tightening torque needed to strip the surrounding bone. The second aim was to identify the percentage of screws that are inserted beyond the stripping limit of the bone (beyond the stripping torque). The surrounding material is described as ‘stripped’ when the torque applied during insertion excessed the maximum that can be resisted by the bone of the screw hole, causing it to yield. The third aim was to assess the association between surgical experience and stripping rates for the test material. The fourth aim was to assess the effect of different instructions given to surgeons on screw tightness and material stripping rates. Finally, the fifth aim was to study the effect of variations in bone density on screw tightness and material stripping rates.

Methods

Due to the nature of the data presented, a systematic review was performed in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidance (Moher et al., 2009). The search strategy employed free and Medical Subject Headings (MeSH) search terms and a combination of keywords relating to qualitative (‘screw tightness’, ‘overtightened’, ‘tightness perception’, ‘screw insertion’) and quantitative screw insertion (‘insertion torque’, ´stopping torque’, ‘stripping torque´’ ‘stopping/stripping ratio’). There were no restrictions on publication dates. MEDLINE, EMBASE, Web of Science and the Cochrane Library electronic databases were searched up to the 31 August 2018. Only articles in English and German were considered. Initial screening was performed in English by the lead author and in German by the second author using translations of the same keywords. Studies with any number of participants and any number of screw insertions were included. All bone models were included (human (in vivo and cadaveric), animal and artificial). For studies to be included for review of screw tightness, stopping and stripping torque values were needed to be reported in order to calculate the tightness as a percentage, if this had not been calculated within the studies themselves. Exclusion criteria were failure to provided results for screw tightness and/or stripping rates for manually inserted screws. Reference lists of included manuscripts were manually scanned for any relevant additional studies. Calculated percentages are presented as integers.

Results

Our literature searches identified 2,158 potentially relevant studies (Figure 2-1).

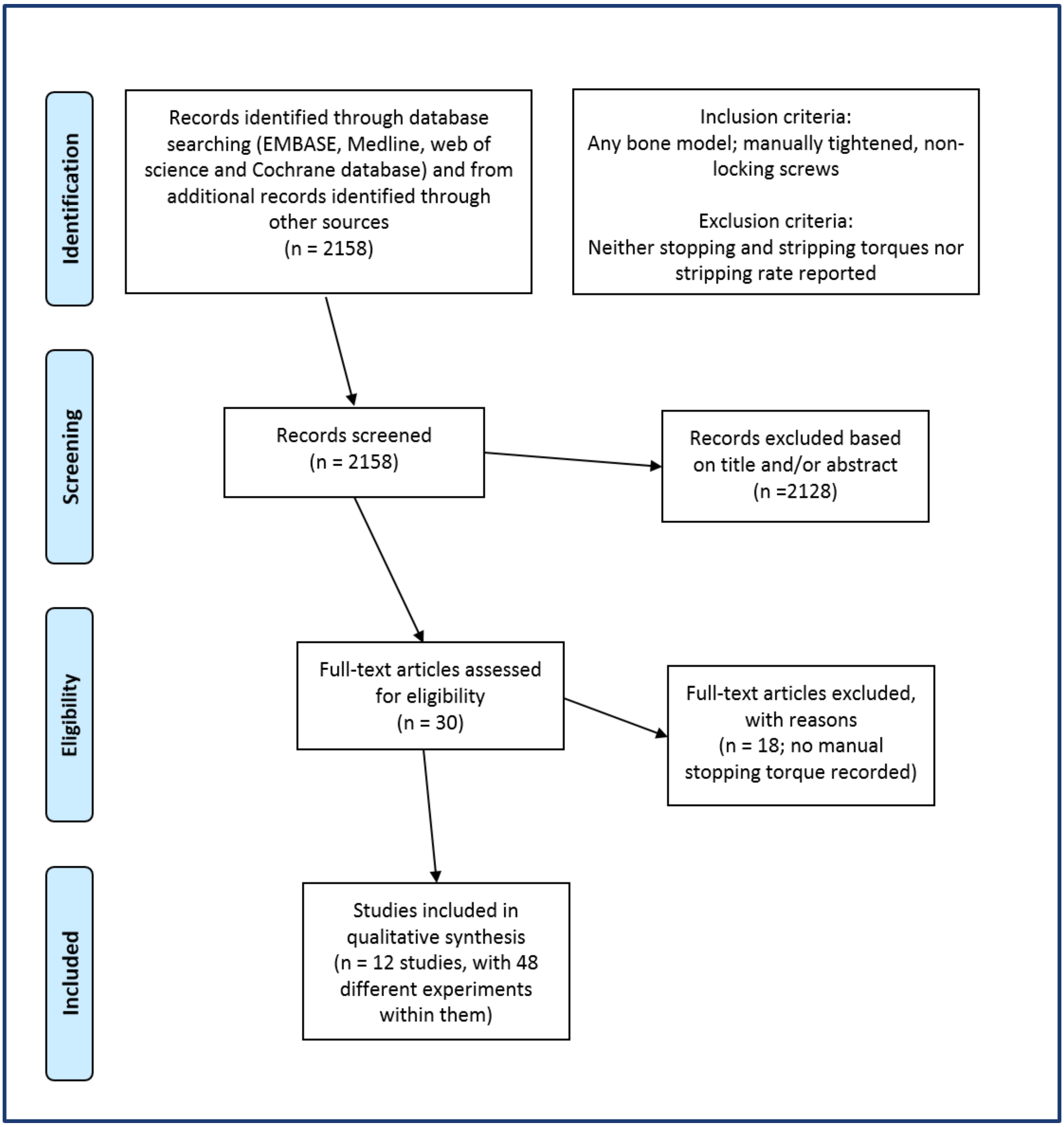

Figure 2-1 - PRISMA flow chart

A further review of the titles and abstracts reduced the potentially relevant studies to 30. On full reading, 18 were excluded as screws were not inserted by hand with the tightness recorded. This process was repeated in German but yielded no further papers for inclusion. The 12 remaining articles were included in the review (Cordey et al., 1980, McGuire et al., 1995, Aziz et al., 2014, Acker et al., 2016, Stoesz et al., 2014, Tsuji et al., 2013, Gustafson et al., 2016, Reitman et al., 2004, Feroz Dinah et al., 2011, Mears et al., 2015, Wilkofsky et al., 2014, Andreassen et al., 2004) for assessment of screw tightness, of which nine reported the stripping rates explicitly in their manuscripts.

Screw tightness achieved as a percentage of the maximum

Several experimental studies have investigated the torque achieved by a surgeon (stopping torque) and compared this to the maximum possible torque. The maximum torque being determined at a separate time interval by using a torque meter to further tighten the screw until the maximum torque value is reached when the material is stripped (stripping torque). By defining the maximum tightness as 100% (stopping torque = stripping torque), the ratio of stopping torque to stripping torque enables presentation of the tightness for that insertion as a percentage of the maximum. Many variables, such as the type of screw used and the material they were inserted into, have been assessed generating a range of different achieved screw tightness by surgeons (Figure 3). The first major work on this topic was published by Cordey et al. in 1980 (Cordey et al., 1980). Sixty-three orthopaedic and general surgeons manually tapped and inserted one 4.5 mm cortical, stainless-steel screw unicortically into one human cadaveric femur, aiming to apply 'optimal torque for a good fixation'. This procedure was repeated with 35 surgeons inserting the same screws into one human cadaveric tibia. Screws were tightened to 84 ±13% (mean ± standard deviation) and 88 ±18%, respectively. The authors found that 10 out of 108 (9%) surgeons; it was not recorded whether this was detected by the surgeons. In the second part of their study, thirty-six surgeons were asked to insert three screws into human cadaveric tibiae using three different methods. Firstly, they assessed the effect of different drilling techniques by using either a large air drill for making pilot holes whilst having radiographs available and being able to see the bone, and secondly in separate holes repeating the first method but with a small air drill instead. Finally, they asked for screws to be inserted with neither radiographs available nor sight of the bone; though methods for blinding surgeons were not stated. None of these experimental setups generated significant differences in screw tightness.

In 1995 McGuire et al. asked 105 orthopaedic surgeons of various experience to insert three titanium and three stainless steel 3.5 mm screws into non-locking plates (McGuire et al., 1995). The instructions to the surgeons were to insert the screws to what they considered 'two fingers tight using their normal technique'. This instruction being a subjective insertion method thought to reduce applicable torque, as a reduced grip is used due to only two fingers holding the screwdriver handle. The stopping torque was measured; however, no assessment of the stripping torque was performed. They found a significant trend for higher stopping torques with more years of surgical experience, a variable that will be explored later in this review. When inserting stainless steel screws, more torque was applied compared to titanium screws. Whilst the number of surgeons employed, and the number of screws inserted (n=315 per screw type (three for each of 105 surgeons)) is the largest of any study to date, this work was limited by the lack of stripping torque assessment, both whether any of the screws were stripped on insertion and whether or not this was detected.

Dinah et al. (2011) had one surgeon inserting 200 screws (160 bicortical, 3.5 mm cortical screws and 40 unicortical, 4.0 mm cancellous screws) into human cadaveric fibulae (Feroz Dinah et al., 2011). They found that, on average, screws were inserted to 71% of the stripping torque. Analysis of their provided data actually shows this value to be 66% given that 83% of the inserted screws were cortical; the stopping/stripping torque ratio was 64%

for cortical screws and 77% for cancellous screws. The range reported was 18% to >100%, with values >100% being calculated as the stopping torque was greater than the stripping torque that could be generated subsequently as the material had already been stripped during the initial tightening episode.

Tsuji et al. (2013) investigated the effect of bone density on tightness, in both human and artificial bone (Tsuji et al., 2013). They measured average tightness for 24 insertions of 3.5 mm cortical screws in Sawbones blocks of eight different densities, 12 insertions of 6.5 mm cancellous screws in Sawbones of seven different densities, three insertions for 3.5 mm cortical screws into each of 16 human cadaveric femurs and two insertions of 6.5 mm cancellous screws into each of 16 cadaveric femoral condyles. Combining all densities, the tightness for cortical and cancellous screws in Sawbones bone blocks were 81% and 77% respectively and in human cadaveric bone, 67% and 85% respectively. They did not report on the percentage of screws that stripped on insertion either quantitatively or subjectively. However, as average ratios were shown, at times averaging 24 tests, and that some tightness averages were 100%, it is likely that some screws stripped the samples on insertion.

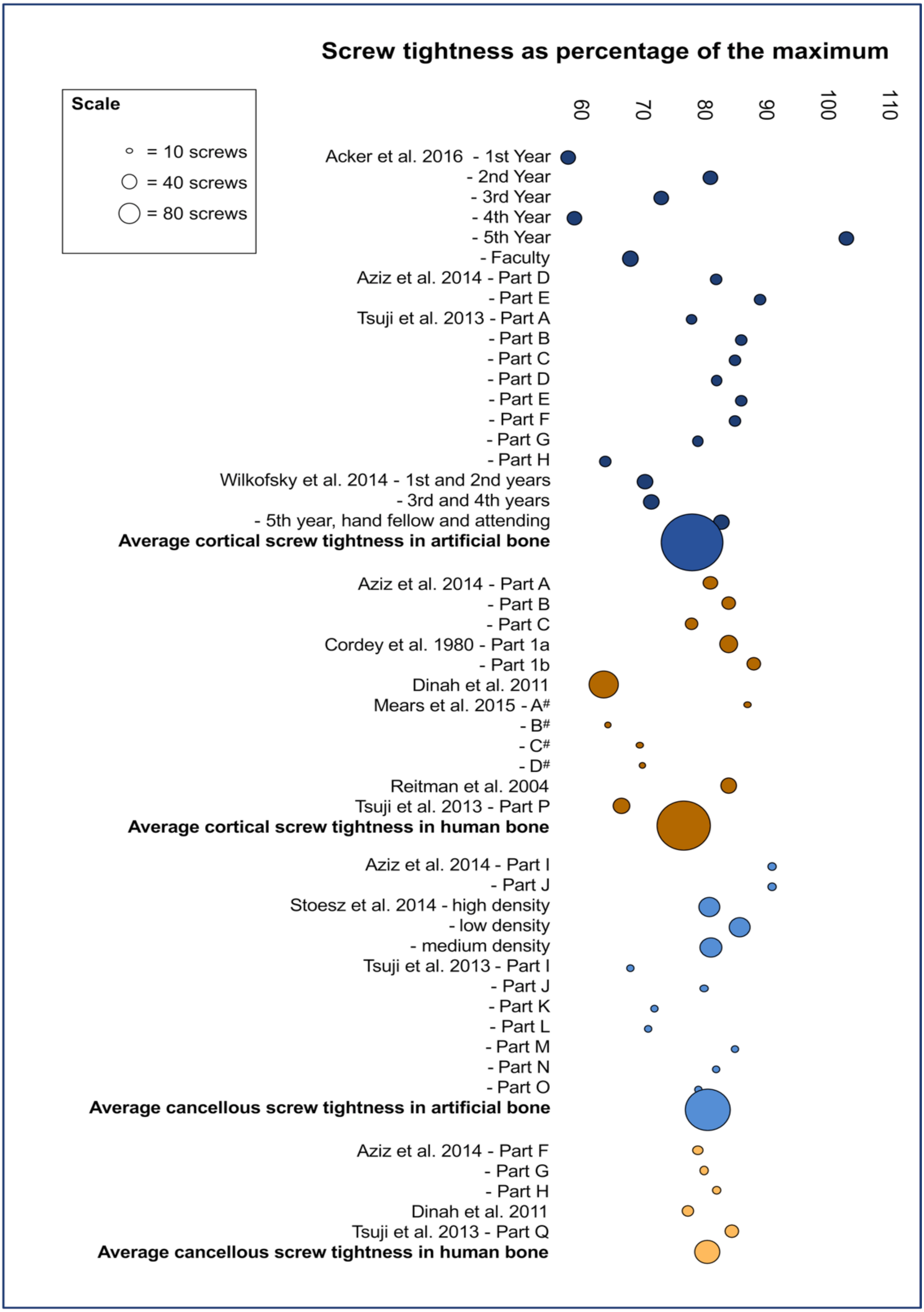
Screw tightness as percentage of the maximum
Scale
= 10 screws
= 40 screws
= 80 screws
60
70
80
90
100
110
Acker et al. 2016 - 1st Year
- 2nd Year
- 3rd Year
- 4th Year
- 5th Year
- Faculty
Aziz et al. 2014 - Part D
- Part E
Tsuji et al. 2013 - Part A
- Part B
- Part C
- Part D
- Part E
- Part F
- Part G
- Part H
Wilkofsky et al. 2014 - 1st and 2nd years
- 3rd and 4th years
- 5th year, hand fellow and attending
Average cortical screw tightness in artificial bone
Aziz et al. 2014 - Part A
- Part B
- Part C
Cordey et al. 1980 - Part 1a
- Part 1b
Dinah et al. 2011
Mears et al. 2015 - A#
- B#
- C#
- D#
Reitman et al. 2004
Tsuji et al. 2013 - Part P
Average cortical screw tightness in human bone
Aziz et al. 2014 - Part I
- Part J
Stoesz et al. 2014 - high density
- low density
- medium density
Tsuji et al. 2013 - Part I
- Part J
- Part K
- Part L
- Part M
- Part N
- Part O
Average cancellous screw tightness in artificial bone
Aziz et al. 2014 - Part F
- Part G
- Part H
Dinah et al. 2011
Tsuji et al. 2013 - Part Q
Average cancellous screw tightness in human bone

Figure 2-2 - Tightness achieved for each part within each study, where measured.
From top to bottom, grouped alphabetically within the following sections: Cortical screws in artificial bone (dark blue), Cortical screws in human bone (dark orange), Cancellous screws in artificial bone (light blue), Cancellous screws in human bone (light orange). All bubbles scaled with size representing number of screws used, e.g. Acker et al. 2016 – 1st year = 40 screws The different components of each study, where relevant, are explained as follows: Acker et al. and Wilkofsky et al. – different years of experience of surgeons; Aziz et al.: A – cortical screws in fresh frozen human bone, B – cortical screws in embalmed human bone, C – cortical screws in dried human bone, D – cortical screws in normal density artificial bone, E - cortical screws in osteoporotic density artificial bone, F - cancellous screws in fresh frozen human bone, G - cancellous screws in embalmed human bone, H - cancellous screws in dried human bone; Tsuji et al. artificial bone: densities for each part (cortical and cancellous screws respectively) – 0.08 g/cm^3 (A and I), 0.16 g/cm^3 (B and J), 0.24 g/cm^3 (C and K), 0.32 g/cm^3 (D and L), 0.40 g/cm^3 (E and M), 0.48 g/cm^3 (F and N), 0.64 g/cm^3 (G and O), 0.80 g/cm^3 (H (cortical only)); Tsuji et al. human bone: P – cortical screws, Q – cancellous screws; Cordey et al. – 1a – 4.5 mm cortical screws in human femur, 1b – 4.5 mm cortical screws in human tibia; Mears et al. - A – 90° past contact of the screw head on the plate; B - 180° past contact of the screw head on the plate; C - two fingers tight; D - 1.4 Nm; Stoesz et al. – high density (0.32 g/cm^3), medium density (0.16 g/cm^3), low density (0.08 g/cm^3).

#Ratio estimated based on provided data, though not explicitly stated by authors.

Table 2-1 - In vitro and in vivo percentages of bone samples stripped, the number of screws used within each study, the number of surgeons involved in descending screw number with methods described. When different variables tested or conditions changed within the same study, results have been separated into different 'parts' indicated with Roman numerals.

Study	Percentage of bone samples stripped (%)	Number of screws inserted	Number of surgeons involved	Methods used
In vitro				
Stoesz et al. 2014	45	240	10	4.0 mm cancellous screws in artificial bone (combined stripping rate for three densities as individual rates not provided)
Dinah et al. 2011	4 (i)	160	1	Screws in human fibulae: i - 3.5 mm cortical inserted bicortically; ii - 4.0 mm cancellous screws inserted unicortically
	28 (ii)	40		
Cordey et al. 1980	9 (i)	108	36	Cortical screws in human tibiae: i – one screw inserted per surgeon under three conditions; ii – one screw per surgeon inserted into three different bone densities
	2 (ii)	90	30 (of the previous 36 used in i)	
Gustafson et al. 2016	42 (i)	80	10	4.0 mm cancellous screws in artificial bone: i - baseline; ii - with visual feedback; iii - after visual feedback removed
	15 (ii)	80		
	35 (iii)	80		
Acker et al. 2016	12 (i)	40	41	3.5 mm cortical screws in artificial bone. i – first year; ii – second year; iii – third year; iv – fourth year, v – fifth year; vi – faculty
	31 (ii)	40		
	24 (iii)	40		
	20 (iv)	40		
	53 (v)	40		
	19 (vi)	48		
Reitman et al. 2004	2	48	1	3.5 mm cortical screws in human vertebrae bodies
Mears et al. 2015	0 (i)	10	1	Cortical screws in human humeri: i – 90° past contact of the screw head on the plate; ii - 180° past contact of the screw head on the plate; iii - two fingers tight; iv – 1.4 Nm
	30 (ii)	10		
	30 (iii)	10		
	20 (iv)	10		
In vivo				
Andreassen et al. 2004	38	225	2	3.5 mm cortical and 4.0 mm cancellous screws in human fibulae
	Average reported stripping rate	Total number of screws	Total number of surgeons	
	26%	1,439	102	

Stoesz et al. (2014) asked five senior resident and five senior practicing surgeons to each insert eight 4.0 mm cancellous screws into polyurethane bone models of three densities (0.08, 0.16 and 0.32 g/cm^3) (Stoesz et al., 2014). Of the 239 screws reported, 131 were successfully inserted without stripping the bone; these had a tightness of 82 ±16%. The remaining screws (108 out of 239) stripped the polyurethane models. They found only a weak correlation (R^2=0.54) between surgeons who were able to insert screws close to, but below, the maximum and those who infrequently stripped screws. They also found that as surgeons inserted more screws in each density, stripping rates increased (p=0.022), however in another paper employing similar methods with eight screws inserted, this effect was not seen (Gustafson et al., 2016).

Acker et al. (2016) asked 33 trainees and eight senior surgeons to insert six screws into bone models with a density of 0.48 g/cm^3, with the instructions to insert to ´two finger tightness´ with their dominant hand (Acker et al., 2016). This was repeated with their non-dominant hand. Dominant hand data showed no significant difference between screw tightness when combining all surgical trainees (74%) and comparing this with faculty (68%); non-dominant hand data was not reported. The variability between participants grouped by years of experience, however, was large with 1st year trainees´ average tightness being 58% and 5th years 103%, i.e. the average for this latter group being beyond the stripping limit of the artificial bone. Additionally, there were large variations in achieved tightness within each group. This is the only study to have investigated the effect of hand dominance, finding a 70% difference in tightness between hands for 1st year surgeons and 9% for senior surgeons.

Reitman et al. (2004) asked one surgeon to insert screws into the anterior aspects of cadaveric human vertebral bodies (Reitman et al., 2004). Initially, one screw was inserted until stripped to establish the maximum torque, followed by a second screw into the same vertebral body to measure the peak perceived torque; this was performed 48 times. They found a tightness of 84%, with only one of these latter screws stripping the bone on insertion (2%).

Two studies used real-time torque feedback via visual displays (Gustafson et al., 2016, Mears et al., 2015). Mears et al. (2015) inserted 10 screws into osteoporotic human humeri at 90° or 180° rotation past the point of first screw head contact, to 1.4 Nm or to two finger tightness. Whilst not explicitly defined, 1.4 Nm was likely chosen as this is 70% of the maximum value for these osteoporotic bones and matches the value found for the optimum tightness in the study by Tankard et al. (Tankard et al., 2013). The torque values that screws were inserted to were recorded, although without direct assessment of the stripping torque. However, based on the assumption that 70% tightness was achieved with the 1.4 Nm tests, tightnesses of 64, 87 and 70% were generated for the different methods respectively. They found that 2/10 screws were still stripped despite targeting a value of 1.4 Nm, with zero, three and two screws stripping the bone using the other insertion methods respectively. This may be explained by the insertion torque that was targeted, and used as a reference, being beyond the stripping limit of the bone, rather than the technique causing it. However, as no assessment of the maximum torque for the bone samples was performed, this remains unknown. The other study to use visual feedback was performed by Gustafson et al. (Gustafson et al., 2016). They asked five senior surgeons and five attending surgeons to insert eight 4.0 mm cancellous screws into polyurethane bone blocks of 0.1 g/cm^3. First, they were asked to insert eight screws to create ‘maximum construct stability’.

Screws causing stripping were recorded, being 42% of all insertions for this component of the study. Next, digital torque readings were displayed during insertion for the surgeon to use as feedback. With visual feedback, the rate of bone stripping reduced significantly to 15% ($p<0.001$). Visual feedback was then removed, with the stripping rate returning to a significantly ($p<0.007$) higher level of 35%, similar to the first part of testing. Awareness of whether the screw holes were stripped was not recorded.

Bone stripping rates

There is very limited research into the rates of bone stripping intraoperatively. A study by Andreassen et al. (2004) investigated the augmentation of screws if the purchase achieved intraoperatively was determined to be inadequate (Andreassen et al., 2004). In their selected patients (those over 50 years old with isolated ankle fractures), they found that a synthetic bone void filler was needed for 38% of screws, with 88% of patients having at least one screw that required this (Andreassen et al., 2004). The remaining data on rates of stripping comes from in vitro studies (Cordey et al., 1980, Gustafson et al., 2016, Stoesz et al., 2014, Mears et al., 2015, Feroz Dinah et al., 2011, Acker et al., 2016, Reitman et al., 2004). The range of mean average stripping rates, when reported, was 0-53% (Mears et al., 2015, Stoesz et al., 2014) (Table 1), though some individuals within studies stripped more; up to 83% (Stoesz et al., 2014). Only 19 of the 48 parts of the experiments within studies examining surgical techniques recorded whether screws were stripped, with stripping being confirmed if the torque created after the surgeon had stopped tightening was quantitatively less than the stopping torque. It may be that there was no concern regarding stripping and/or no occurrence of this, explaining why it was not reported. Even when the stripping rates are described, this potentially overlooks the screws inserted beyond the yield torque for the material if recording relies on surgeons’ perception. Dinah et al. (2011) reported 9% (18/200) of samples being stripped inadvertently, however they also graded unstripped insertions, finding a further 12% (24/200) were deemed to have been overtightened (90-99% of maximum torque) (Feroz Dinah et al., 2011).

Few papers have assessed surgeons´ subjective abilities to detect whether they had stripped the screw. Gustafson et al. (2016) showed no correlation between occurrence and the perception of stripping (p=0.768) (Gustafson et al., 2016). With visual feedback, there was increased accuracy in predicting stripping, as one would expect if able to watch a digital readout of the applied torque. However, surprisingly stripping still occurred in 15% of insertions. No data were provided for the rate of accurate predictions when visual feedback was removed, though it was reported as being significantly (p=0.008) better than the 6.1% prediction rate at the start of the experiments. Interestingly, when the visual feedback was removed, whilst the improved perception of stripping was partially maintained, there was no significant reduction in the rate of stripping overall, potentially showing a reliance on augmented feedback. This is also the only study that has investigated any retention of a new method or improvement in technique, though over a very short time period, i.e. within the same experimental setting. Stoesz et al. (2014) found 45% of screws were stripped on insertion, yet only 10 of 109 (9%) of stripped screws were identified correctly (Stoesz et al., 2014). Identification only occurred when significantly (p=0.005) past the stripping torque (residual torque being 55% of the maximum, compared to 80% when not detected).

One study attempted to quantify practitioners´ confidence with the screws they inserted (Siddiqui et al., 2005). Siddiqui et al. asked one nurse, one junior surgical trainee, one senior surgical trainee and one consultant to insert 4.0 mm partially threaded cancellous screws into chipboard and asked them to assign each insertion (n=30, 43, 35 and 34 respectively) a score 0-10; with 0 being very weak and 10 being very strong. Each screw then underwent axial pullout. They found correlations between axial pullout force and confidence scoring of $r^2 = 0.34, 0.26, 0.22$ and 0.45 respectively. Unfortunately, the material used, the lack of torsional force assessment or whether samples were stripped on insertion, and the variability in the material properties between different chipboard samples greatly limits the generalisability of these findings to clinical practice.

The effect of surgical experience on screw tightness and stripping rates

Stripping rates appear to be individual to each surgeon, with a wide range of performance. There is both intra- and inter-surgeon variation in insertional torque (Acker et al., 2016). A stark example of variations between surgeons is seen in Gustafson et al. (2016) where, when inserting screws without visual feedback, one of their 10 surgeons stripped 16 out of 16 and another 15 out of 16 samples (Gustafson et al., 2016). Conversely, of their 10 surgeons, two stripped none, and a further two only stripped one sample when there was no visual feedback.

The torsional force applied to screws increases with more surgical experience (McGuire et al., 1995, Wilkofsky et al., 2014, Acker et al., 2016), but this also increases the rate of stripping (Acker et al., 2016). Wilkofsky et al. (2014) found that more experienced surgeons applied significantly more torque to screws than either 1st and 2nd years (p=0.003) or 3rd and 4th year surgical trainees (p=0.007) (Wilkofsky et al., 2014). This resulted in a greater tightness of 83 ±12% compared to 70 ±19% and 71 ±20% respectively. Whilst the variation in tightness was less for the most experienced surgeons than other groups, the lateral motion generated whilst creating the higher insertional forces, i.e. non-coaxial insertion or ‘screw wobble’, was approximately 56% larger ($p<0.05$). This study also found that the number of screw rotations varied greatly between surgeons, ranging from four to 21 revolutions being needed when inserting a 3.5 mm cortical screw into polyurethane bone (Wilkofsky et al., 2014). Apparently contradicting these findings, as previously stated, Acker et al. (2016), found no significant difference in the applied torque between 1st (junior) and 5th year (senior) trainees, nor when compared to senior surgeons. Generally, concerns during screw insertion are related to the balancing of the appropriate minimum tightness for the construct to generate sufficient purchase and resistance to failure during locomotion, against overtightening the screw and causing bone stripping. However, more trainee experience appears to lead to an increased chance of this more detrimental, latter situation occurring (Acker et al., 2016). As no optimum tightness was established for the bone model used in their study (as functions of compression and pullout strength) it is unknown how tight screws should have been inserted, just that stripping the bone should have been avoided. Stoesz et al. (2014) found no relationship between stripping rates and surgeon experience ($p=0.437$), but comparing ten surgeons, there were significant differences in stripping rates between individuals ($p<0.001$) (Stoesz et al., 2014); the percentage of samples stripped ranged from 17% to 83%. Seven of the 131 unstripped screws were thought by surgeons to be stripped, however six of these reports were from one surgeon. These two aspects strongly justify having multiple surgeons within the methods for any study investigating techniques to reduce the impact from different abilities, or at least ensuring that potential variations between surgeons are considered and reported.

Effect of different instructions to surgeons on screw tightness and stripping rates

With the exception of one paper that compared four different instructions (Mears et al., 2015) and the in vivo study (Andreassen et al., 2004), the orders given to surgeons during these studies fall into five categories: subjective feeling of tightness (Tsuji et al., 2013, Aziz et al., 2014), ‘two fingers tight’ (Feroz Dinah et al., 2011, Wilkofsky et al., 2014, Acker et al., 2016, McGuire et al., 1995), optimal for good fixation (Cordey et al., 1980), maximum construct stability (Gustafson et al., 2016, Stoesz et al., 2014) or maximum holding force without stripping the bone (Reitman et al., 2004). There are no direct comparisons between different instructions to surgeons to know whether any of these methods make a difference to the techniques employed. ‘Two fingers tight’ has been reported to be the gold standard for screw insertion, if performed by an experienced orthopaedic surgeon (Mears et al., 2015) and what is commonly taught in theatres to trainee surgeons in the USA and Europe (Acker et al., 2016, Thakkar et al., 2014). However, the evidence that this technique improves screw insertion is limited, and subsequently, when evaluated, has shown to be incorrect in that it does not lead to a consistent level of torque being applied (Acker et al., 2016, Ryan et al., 2015). Further to this, previous work, such as Cordey et al. (1980), has been reported by others to have used two finger tightness (Mears et al., 2015, Tankard et al., 2013), despite not defining this in their methods (Cordey et al., 1980). Targeting a specific tightness and comparing surgeons’ abilities to repeatably and accurately achieve this target versus other tightnesses has not been investigated, nor has the effect of different instructions on the same physical variables.

Effect of variations in bone density on screw tightness and stripping rates

A common issue with biomechanical research is the model used for testing. It is established that artificial bone models reduce variability, costs and ethical concerns. However, they do not demonstrate many of the biomechanical characteristics of real bone, such as cortical porosity and failure mechanisms, thus limiting generalisability from any research using them. In contrast, in vitro cadaveric human and animal bone models will generate more realistic resistances to screw insertion, but the variability in some models, even between contralateral pairs (Diederichs et al., 2006), means that appropriately powered results can be difficult to generate. Some animal models (Fletcher et al., 2018b, Fletcher et al., 2018a) address these issues, but ultimately unless in vivo human bone is used, results may not be fully translatable into clinical practice.

Nicayenzi et al. (2012) showed no significant difference between human and artificial femora cortices when inserting cortical screws in terms of the stripping torque when normalised to adjust for changes in bone geometries, measured by the bone-screw interface area: normalised stripping torque = stripping torque/(π · screw major diameter · cortical thickness) (Nicayenzi et al., 2012). When comparing maximum torque to the plateau torque during insertion, and comparing these as predictive variables, Reynolds et al. (2013) found no difference between ovine and human bone maximum torques ($p=0.331$). Despite also using synthetic bone blocks, they did not report if there were significant differences in comparison to these (Reynolds et al., 2013).

Aziz et al. (2014) compared fresh frozen, embalmed and dried adult human humeri alongside normal and low density synthetic bones (Aziz et al., 2014). They found that when one surgeon inserted cortical screws to 'a subjective feeling of tightness', there was no difference in the tightness between any of the models used. With cancellous screws, one difference was detected with the tightness being 13% lower ($p<0.05$) in fresh-frozen bone than in artificial osteoporotic bone, though the authors reported that all comparisons were underpowered.

Tsuji et al. (2013) showed for cortical screws in synthetic bone, as density increased from 0.08 to 0.80 g/cm^3, screw tightness decreased ($R = -0.63$), yet in human cadaveric femora, there was no difference with density changes (Tsuji et al., 2013). For cancellous screws in artificial bone models, they found as density increased from 0.08 to 0.64 g/cm^3, screw tightness increased ($R = 0.59$), yet in human cadaveric femora, the opposite was seen ($R = -0.56$). This shows the potential variability in the insertion technique of the same individual, given that with different screws in the same material or the same screw in different material, different trends were seen each time. All other studies involving human bone did not have any comparison with artificial models (Cordey et al., 1980, Feroz Dinah et al., 2011, McGuire et al., 1995, Andreassen et al., 2004, Reitman et al., 2004, Mears et al., 2015). Studies just using artificial bones have shown neither an effect on achieved tightness ($p = 0.299$) nor on stripping rates due to bone density ($p = 0.186$) (Stoesz et al., 2014).

Unassessed variables

Numerous variables related to the practical insertion of screws have not been investigated. No studies have compared different sizes of the same style screw (i.e. cortical screws with outer screw thread diameters of 3.5 mm and 4.5 mm) within the same group of participants or bone models. This would provide information on the ability of surgeons to adapt to different commonly used screw sizes and whether different size screws are more prone to stripping. Studies directly comparing cortical and cancellous screw insertion techniques are limited as either the number of cortices engaged is different (Feroz Dinah et al., 2011) and/or the outer diameter of the screw is considerably greater for cancellous screws (Aziz et al., 2014, Tsuji et al., 2013). No tests on the effect of cortical thickness on the screw tightness generated by surgeons have been performed, which could highlight situations where extra care was required to prevent bone stripping.

No analysis of the contributions of cancellous and cortical bone have been performed to elucidate which aspects contribute most to the proprioceptive feedback experienced by a surgeon in the presence of both classes of bone. Cancellous bone density and microarchitecture have been shown to affect insertion failure torques (Ab-Lazid et al., 2014) though not the tightness applied by surgeons. Focussing on screw insertion into cancellous bone may be important, given that the density of this bone is less than that of cortical, and thus stripping rates are higher. Some studies have focused on a pure cancellous model, i.e. no cortical shell present (Stoesz et al., 2014). Whilst this highlights a situation where bone damage may be easier to cause, all clinically inserted non-locking screws are likely to have a near cortex of bone, and if this is greater than 1.5 mm, the role of the cancellous bone has been shown to be limited (Seebeck et al., 2005).

Other practical surgical variables are yet to be investigated. Whilst it is expected that gloves were worn by surgeons during experiments, and certainly during in vivo testing (Andreassen et al., 2004), no studies explicitly stated their use, despite it being unknown if different types of gloves (such as unsterile compared to sterile), or number of layers (single compared to double layer) affect screw tightness. The effect of screw and screwdriver variables may additionally impact of screw tightness; aspects such as screw head shape, handle shape and present or absence of a washer or plate.

Limitations

There are limitations with this review. Firstly, some assumptions have been made when analysing the data provided by authors, such as assuming that 1.4 Nm was chosen by Mears et al. (2015) as this reflects 70% of Tmax for osteoporotic samples in the study by Tankard et al. (Tankard et al., 2013). Secondly, there is only one in vivo study reported, likely due to the difficulties with measuring or predicting the stripping torque intraoperatively without causing additional damage to the bone. Thirdly, no screws smaller than 3.5 mm outer diameter have been assessed, nor have screws of different shapes such as those with conical inner and outer diameters. There may be limited generalisability of the findings of these studies to other situations. Finally, what values have been used to calculate tightness are unclear in some studies. If the torque applied during insertion is greater than the torque that can subsequently be applied when attempted to strip the surrounding material, when converting this to a percentage of the latter, values greater than 100% will be calculated. If these are included in the mean average, it will skew results, such as the 5th year residents in the study by Acker et al. reported a mean of 103%. Future studies can eliminate this skewing factor by reporting the unstripped tightness and stripping rates.

When summating all the screw insertions within the 12 different studies in this review article, a total of 260 surgeons were involved. These surgeons inserted a total of 2,793 screws, an average of 11 screws each, although only 1,510 screws have been inserted by 145 surgeons where the tightness was measured. The maximum number of screws inserted under the same in vitro conditions with one surgeon is 160 but only eight if more than two surgeons were used (Figure 2-3).

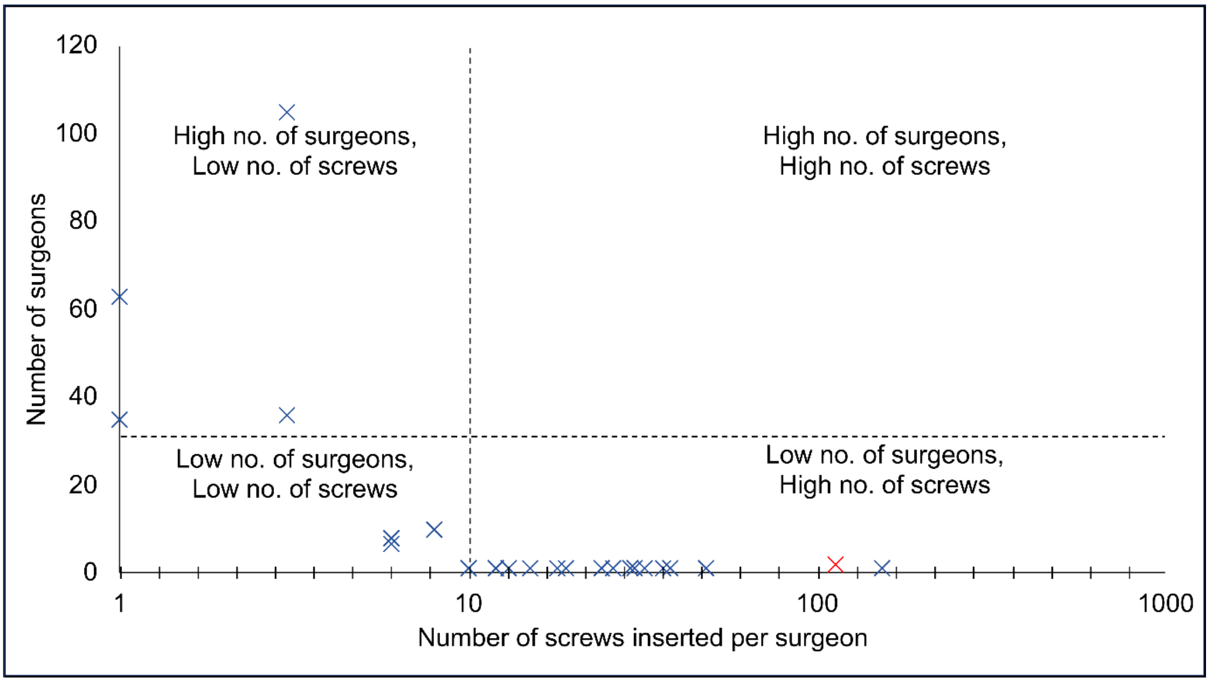

Figure 2-3 - Number of surgeons and the number of screws each inserted within each part of each study (12 studies reviewed in this manuscript, 48 experiments in total), with the latter displayed logarithmically. Blue markers indicate in vitro studies, red marker for the sole in vivo study (Andreassen et al., 2004). High/low surgeon and screw number quadrants created based on more or less than 30 surgeons and more or less than 10 screws inserted by each.

Thus, an average is used to describe the behaviours of the entire orthopaedic, and potentially wider, communities such as maxillofacial, plastic and neurosurgery. Further to this, the optimum tightness for primary fixation is currently unknown (except for it being below the stripping torque). Additionally, the effect that screw tightness has on fracture healing remains unknown and would require complicated in vivo studies given the multifactorial nature of bone remodelling; in vivo tightness and its effects on healing may be very different to the biomechanical experiments performed on non-living tissues. Thus, all assessments of techniques are limited as even if repeatable screw tightness is achievable, which appears not to be the case, these values for tightness may not what is required to generate optimal fixation.

Conclusions

Considerable variation has been found in the tightness applied to screws by surgeons, with combined averages of 78 ±10% for cortical screws and 80 ±6% for cancellous screws across all studies. When specifically investigated, nearly 26% of all screws have been found to have stripped the surrounding bone during insertion, with most of these occurrences being undetected by the surgeon. Large variation between different surgeons has been found, with some studies finding contradictory outcomes with regards to whether more surgical experience is associated with improvements in tightness or rate of stripping. Whilst some variables have been investigated for their impact on screw tightness, such as the effect of different bone densities, many remain unexplored. Future work to establish the influence from different intraoperative situations such as cortical thickness and screw diameter could highlight areas where extra vigilance is needed to avoid overtightening of screws, whilst all future studies should have multiple surgeons to reduce the risk of individual surgeon biases. Further research establishing the optimum tightness for screw constructs is needed to help surgeons by providing a target torque for each screw, alongside integration of automating torque detection during screw insertion to prevent excess damage being caused. The development of augmented screwdrivers able to indicate the optimum and maximum torques for any given situation would greatly help with surgical education and clinical performance. This could make screw insertion more efficient through higher quality screw fixation generating more secure constructs, reducing fixation failure rates.

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2.4 Summary

The literature review identified that the optimum tightness for screws was not known. Most reports of what screw tightness should be were based on what surgeons achieved *en masse* rather than what they should be achieving. This seemed to be completely inverted from what should be happening, i.e. surgeons should be adapting their techniques to the evidence, rather than the other way round.

Most studies into screw tightness (both achieved and what optimum tightness might be) were underpowered and/or limited by having either very few surgeons insert screws or many surgeons insert very few screws. Another key finding was the high rates of screw hole stripping that occurred. This was concerning, considering that all but one of the included studies were performed in vitro, where the person(s) inserting the screws knew that their technique was to be tested; it might be expected that extra care would be used knowing that their screw insertion outcome was to be critiqued and that perhaps intraoperative performance might be even worse. The small number of samples and repeats within the experiments highlights two things. Firstly, that there may not be appropriate models available for performing appropriately powered studies and secondly that the number of confounders and variables present when inserting screws is underappreciated.

I was surprised to find that such a common practice as screw insertion was so poorly understood and not greatly investigated. Screw insertion is one of the first surgical skills that a young surgeon encounters and has to learn, yet it appears that what needs to be taught is not known or understood. This appeared to be a case of ‘theory induced blindness’, described by Daniel Kahnemann where a key aspect of a principle had been overlooked (Kahnemann 2011) despite being a very common activity. Finding such variability in screw insertion performance, and a lack of known targets for best performance needed exploring. It also became apparent that controlling screw insertion within biomechanical studies might be difficult if there was no known tightness to be consistently targeting within testing. Thus, there may be a known potential confounder in all biomechanical testing unless stated that insertion conditions, such as the torque applied, were controlled for.

Whilst artificial bone models were used in several of the studies, there seemed to be a gap between using artificial bone and then using human tissue. Thus, there would be a large role for a non-artificial bone model, so long as it did not have the financial and ethical restrictions of human tissue experiments. Additionally, with an increasing prevalence of osteoporosis, and the increased risk of fixation failure in this patient group, there is a need for bone models to be able to mimic this condition. I had found other groups who had chemically altered bovine vertebrae to mimic low density bone and felt that applying this to a long bone model would be worth exploring.

The use of real-time feedback in two of the studies (Gustafson et al., 2016, Mears et al., 2015) seemed very logical to me, and a technique used in other engineering disciplines when the applied torque needs to be known. Even if the targeted torque is not known, having a sense of the force that is applied, and perhaps what force caused the screw to strip, would allow real-time calibration of what torque should be applied. I was able to find engineering equations that can be used to predict the maximum torque for a screw hole, and screwdrivers that can indicate the applied torque in real-time and planned to explore the used of these techniques in improving performance for screw inserters.

Many factors might affect screw insertion, and screw-inserter performance was tested and measures in many different ways in the studies reviewed from the literature.

This raised more questions about how performance is controlled for not only in surgery but also in biomechanical research. Indeed, no work had the perspective of confirming how good and reliable biomechanical researchers are at putting screws in, yet the experiments performed by biomechanical researchers form the basis of many new techniques and implant systems that are clinically used. Alongside this, screw insertion relies on proprioceptive control and dexterity, but these skills are likely to change based on the insertion conditions, such as the screwdriver used or the type of screw inserted. Any potential impact from variables such as these again had not been explored but could greatly impact both research and clinical screw performance.

Following the literature review, the objectives were identified for the research project as:

1. Develop and validate a novel model for biomechanical research to enable appropriately powered biomechanical tests and to model both normal and low-density bone conditions (Chapter 3).
2. Identify the optimum tightness for screws as a function of the compression and pullout forces generated. This would initially be investigated using an animal model (Chapter 4), then validated using human, cadaveric bone (Chapter 5).
3. Investigate the impact on screw tightness and screw hole stripping rates of different insertion conditions, firstly so that future research projects involving screws could be appropriately controlled – reducing the impact of known confounders – secondly so that screw insertion in clinical practice could be informed of the impact from different situations such as using a non-dominant hand, or the thickness of the cortex the screw was inserted into, and thirdly to investigate if screw insertion

performance could be improved using an augmented screwdriver that indicated the optimum tightness for a screw whilst being inserted (Chapter 6).

4. Explore the performance of orthopaedic surgeons and biomechanical researchers when inserting screws, and to test the benefits of using augmented screwdrivers (Chapter 7).

Chapter 3 – Developing a new model for in vitro biomechanical testing of screw fixation

3.1 Context

Biomechanical research remains a high priority in orthopaedics. Accurate and reliable biomechanical models are needed to ensure the maximal clinical transferability of research findings. However, current bone models, especially those for osteoporosis, can be expensive and/or hard to obtain. Whilst human specimens require ethical approval for their use and are associated with higher variability that animal specimens, alternatives such as artificial bone models fail to adequately represent real bone properties. In vivo osteoporotic animal models can be made, however the costs associated with these are often prohibitive and can have variable accuracy in mimicking the desired bone target. Bovine vertebrae have been used as a model for biomechanical testing and successfully modified using acid degradation protocols to mimic osteoporosis. However, no long bone model of osteoporosis has been created using these techniques nor have long bovine bones been validated as a biomechanical model. There is a need for an animal bone model that can provide numerous, homogeneous and inexpensive samples to enable appropriate powering of future studies. The aim of this chapter was to establish and validate (biomechanically) a bovine model of normal density and of low density, including investigating which bovine long bone to use and how to reduce its bone mineral density.

Data can be freely access for the following paper from: https://doi.org/10.15125/BATH-00410.

3.2 Statement of Authorship

This declaration concerns the article entitled:

Juvenile bovine bone is an appropriate surrogate for normal and reduced density human bone in biomechanical testing: a validation study.

Publication status (tick one)

Draft manuscript	☐	**Submitted**	☐	**In review**	☐	**Accepted**	☐	**Published**	☑

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Statement from Candidate	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature.		
Signed		**Date**	07/08/2021

3.3 Study 2: Juvenile bovine bone is an appropriate surrogate for normal and reduced density human bone in biomechanical testing: a validation study

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Abstract

Orthopaedic research necessitates accurate and reliable models of human bone to enable biomechanical discoveries and translation into clinical scenarios. Juvenile bovine bone is postulated to be a potential model of normal human bone given its dimensions and comparatively reduced ethical restrictions. Demineralisation techniques can reduce bone density and alter bone properties, and methods to model osteoporotic bone using demineralised juvenile bovine bone are investigated.

Juvenile bovine long bones were quantitatively CT scanned to assess bone density. Demineralisation using hydrochloric acid (0.6, 1.2 and 2.4 M) was performed to create different bone density models which underwent biomechanical validation for normal and osteoporotic bone models.

All long bones were found to have comparable features to normal human bone including bone density (1.96 ± 0.08 gcm^{-3}), screw insertion torque and pullout strength. Demineralisation significantly reduced bone density and pullout strength for all types, with 0.6 M hydrochloric acid creating reductions of 25% and 71% respectively.

Juvenile bovine bone is inexpensive, easy to source and not subject to extensive ethical procedures. This study establishes for the first time, the use of its long bones as surrogates for both normal and osteoporotic human specimens and offers preliminary validation for its use in biomechanical testing.

Keywords

Bone µCT; Biomechanics; Osteoporosis; Injury/fracture healing;

Introduction

Orthopaedic research necessitates access to accurate and reliable models of human bone to enable biomechanical and clinical advancements. A significant clinical driver for orthopaedic research is the increasing rate of fractures, particularly in patients with osteoporotic bone. Given the high failure rate of fracture fixation (Broderick et al., 2013, Goldhahn et al., 2008) improvements in fracture fixation are urgently needed for which the underlying research requires reliable and readily available specimens. Thus, the impact of improvements in available experimental bone models is becoming ever greater. Various cadaveric and in vivo animal models are available for experimental testing of methods and screw designs for fixing fractures, with the option available to alter their material properties through demineralisation using chemical treatments. However, all models are associated with limitations. Cadaveric human bone often only represents an older demographic of the population and the interspecimen variability (Hobatho et al., 1992, Cowin, 1989) means that large numbers are needed to appropriately power studies. There are also ethical constraints associated with the procurement, storage, usage and disposal of human specimens. Models using in vivo modification of animal bone have been established, such as ovariectomised animals, but these can fail to produce the desired bone properties (Paschalis et al., Egermann et al., 2005), such as only mildly reducing bone density, whilst having macroscopic dimensions that are unrepresentative of human bone.

Unmodified in vitro animal models may have baseline properties incomparable to human bone, such as a higher volumetric bone mineral density (vBMD) and thicker cortices. Some of these characteristics can be modified with chemical treatments, such as hydrochloric acid (HCl), to demineralise the bone (Nichols and Bachus, 2014, Akbay et al., 2008, Ching-yi Lee et al., 2011, Figueiredo et al., 2011), however the macroscopic dimensions such as length and diameter cannot. Despite 55-80% of fractures involving long bones (Van Staa et al., 2001, Zebaze and Seeman, 2015), no in vitro model using demineralisation techniques (or variants thereof) has been used on long bones; these methods have only been employed in limited instances using spinal vertebrae (Nichols and Bachus, 2014, Akbay et al., 2008, Ching-yi Lee et al., 2011, Figueiredo et al., 2011).

Bovine bone has been used for modelling normal and osteoporotic bone, and has been shown to have high reliability (Akbay et al., 2008). However, the macroscopic properties of mature bovine long bones reduce their modelling accuracy as they are longer, with much thicker cortices than human bone. This limits the validity of the test and the transferability of any biomechanical results to human in vivo clinical applications. Following the observation that juvenile bovine bone has comparable macroscopic dimensions to adult human bone, further investigation into the use of this as a model was postulated. Juvenile bovine bone has neither been investigated for its potential to biomechanically model human long bone, nor as a potential model of osteoporosis once demineralised. If the model is shown to be valid, this will offer a substantial change to testing practice as it represents an economic and viable alternative to the more expensive methods used currently. Also, it will offer a controllable way of reproducing the variability seen in human samples; human bone characteristics are variable, but in biomechanical testing variables need to be controlled and validated demineralisation techniques potentially offer this.

Our objectives were to establish and validate juvenile bovine bone as an appropriate model for biomechanical testing. First, we established whether the volumetric bone density (vBMD) of juvenile bovine long bones is comparable to literature quoted values for adult human bone. Secondly, we assessed the effect of acid demineralisation on vBMD, aiming to reduce vBMD to replicate osteoporotic bone. Using different modification and preparation techniques, our tertiary objective was to analyse one specific type of long bone in detail (this bone being chosen based on its vBMD and ease of use) to assess if the modification techniques, including dehydration of samples, would reliably reduce the vBMD to create a spectrum of osteoporotic bone models. Our final objective was to validate the models using pull-out testing; this being the key requirement of a model being used for fracture fixation testing.

Methods

Four variants of long bones (humerus, ulna, femur and tibia) from 4 to 5-month-old calves were obtained from a commercial butcher (Bartlett and Sons, Bath, UK). All soft tissues, residual trabecular bone and metaphyseal areas were removed, before the remaining cortical diaphyses were sectioned using a circular saw into 15 mm length cross sections (Figure 3-1); generating six samples per bone. The diaphyseal portion of the long bones was selected due to its more cylindrical shape and ease of use. Three specimens of each of the four long bone variants were used, each cut into six sections, generating 18 samples for testing under three conditions, detailed below (n=72). Bone sets were amalgamated from the three different bones of each variety so that any variation in bone density between samples would be negated (Figure 6).

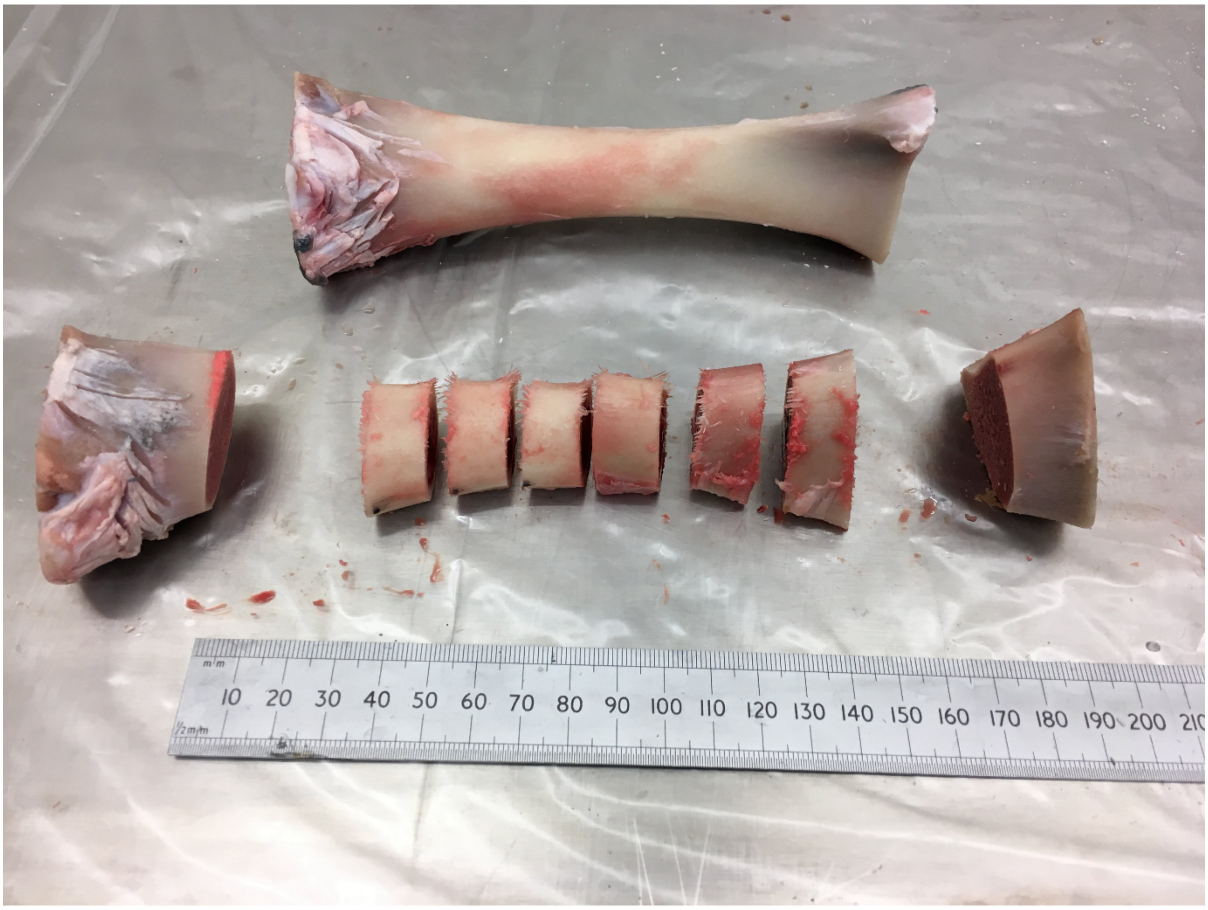

Figure 3-1 - Sectioning of long bone diaphysis, with six cut diaphyseal samples retained for testing.

Based on preliminary data, non-inferiority power calculations showed that 12 samples would be needed to be 90% sure that the lower limit of a 90% two-sided confidence interval would be found at a non-inferiority limit of 0.10 gcm^{-3}. Each section was clamped and 2.5 mm pilot holes were perpendicularly drilled using a bench drill, with the holes spaced equally around the circumference, at least 8 mm apart, with no more than six holes per sample.

Initially, assessment of volumetric bone mineral density of the four long bone variants was achieved by performing quantitative micro-CT analysis (X Tec, XT H 225 ST, Nikon Metrology UK Ltd, Derby UK) of all samples before treatment; scanning protocols were the same for all samples (162 kV, resolution 0.2 mm) (Figure 3-2). To assess the effect of demineralisation, 12 sets containing six samples were randomly selected (n=72), weighed and placed in the three following solutions: reverse osmosis (R/O) water for 48 hours, 2.4 M HCl for 24 hours and 2.4 M HCl for 48 hours. For the 48 hours treatments, the solutions were changed at 24 hours. Each set was placed in a container of 1.5 l of solution to ensure that there would be an excess of demineralisation solution (>21 cm^3 of HCl per 1 g of bone) (Figueiredo et al., 2011).

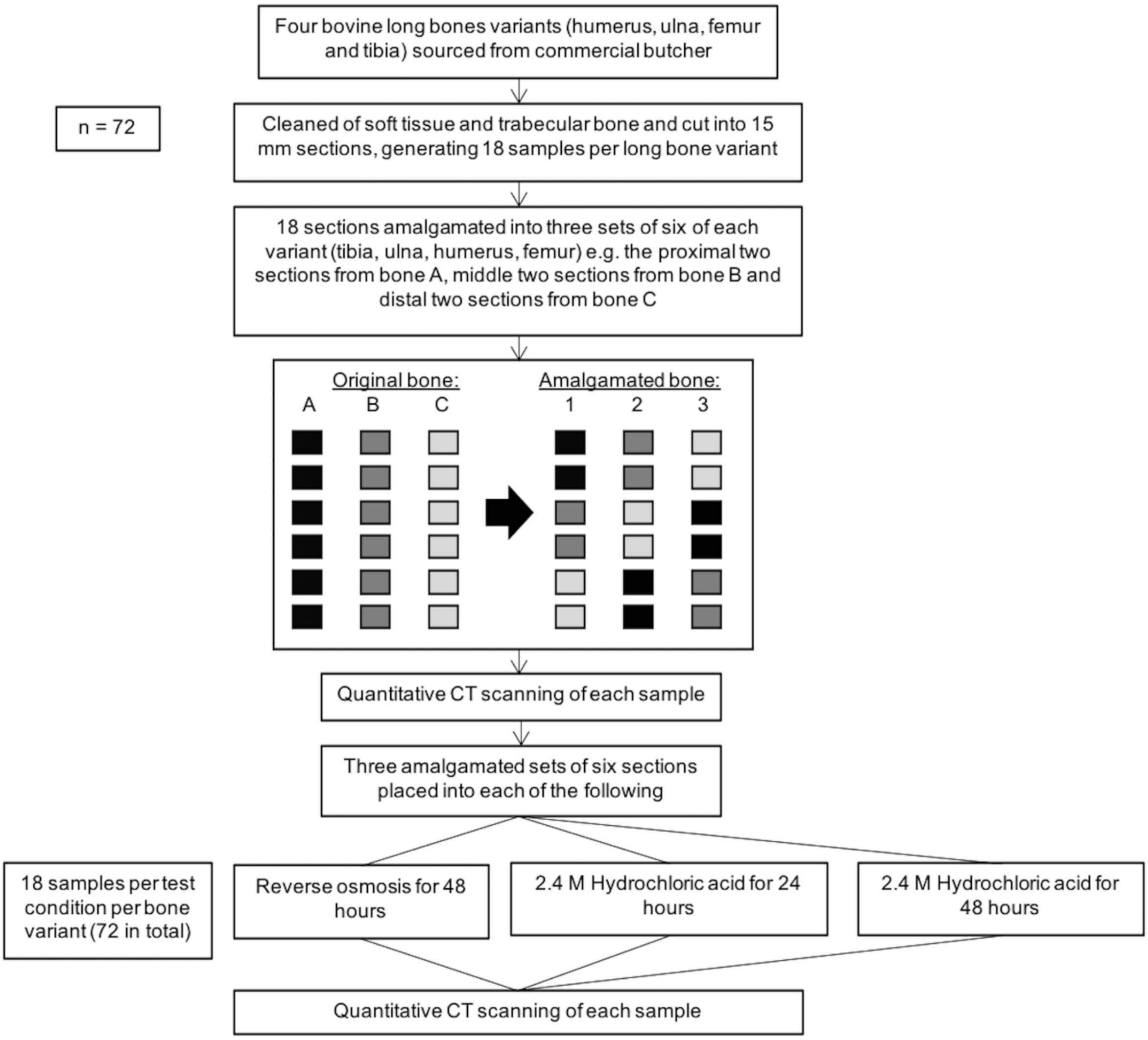

Figure 3-2 - Preparation of long bone variants for bone mineral density measurements.

Specimens were placed in a fume cupboard at 21°C for the desired time period. Samples were thoroughly washed with running water following treatment, until a neutral pH was achieved. Samples then underwent repeat micro-CT scanning. Analysis of the CT data was performed using Simpleware ScanIP (Synopsys, Inc., Exeter, UK (release version 2017)). Phantoms of known density were used as controls, allowing for calibration of the CT grayscales to vBMD using linear regression.

Following quantitative analysis of the four variants' dimensions and vBMD, further testing of preparation and demineralisation techniques was performed on tibial samples, due to their long, straight diaphyseal portion. Ten tibiae were prepared as before (giving n=60 test specimens) (Figure 3-3).

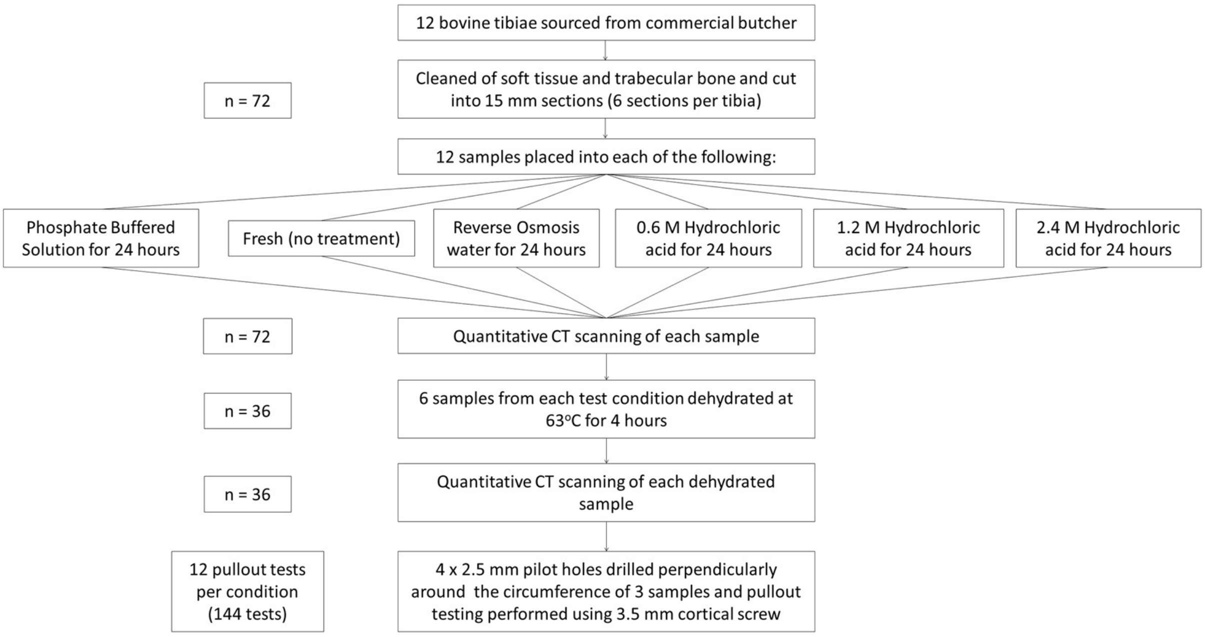

Figure 3-3 - Preparation and testing of samples for different preparation and demineralisation techniques.

Samples were tested under each of the five following conditions: fresh (tested within six hours of slaughter), R/O for 24 hours, phosphate buffered solution (PBS) (Sigma Aldrich Co. Ltd., Irvine, UK) for 24 hours, 0.6 M HCl for 24 hours, and 1.2 M HCl for 24 hours. To assess the impact of drying of the samples, half of the samples (n=30) were tested under the same five conditions but with the samples being dried for four hours at 63°C following removal from their solution; generating ten test conditions for the tibial samples. Again, quantitative micro-CT analysis was performed pre and post treatment.

Pullout testing

Following CT scanning, samples underwent biomechanical testing. Small fragment cortical trauma screws (3.5 mm diameter, 18 mm length, (Stryker, Newbury UK)) were manually inserted into the predrilled holes by the same, experienced orthopaedic surgeon mimicking clinical insertion methods (n=144, 12 per test condition). The insertion torque was continuously recorded using a digital torque screwdriver (Torqueleader, MHH Engineering co. Ltd, Guildford, UK) to ensure that the predicted theoretical maximum insertion torque was not exceeded. The stripping torque was predicted using theoretical equations for the maximum which were adjusted based on the observed material properties of pilot samples (Troughton, 2008). Screws were tightened to 0.5 Nm for all except demineralised samples where a stopping torque of 50% of the stripping torque was chosen, to ensure that the stopping torque was below the stripping torque.

Cortical thickness, which dictates the number of screw threads engaged within the bone, correlates with pullout strength(Chapman et al., 1996), thus the relationship between cortical thickness and pullout strength was established using linear regression analysis. The cortices were measured using digital callipers (Figure 3-4), assessing both proximal and distal aspects of the sample, with the mean value used for each sample.

Figure 3-4 - Measuring cortical thickness of juvenile bovine sample.

The relationship between cortical thickness and pullout force was recorded for each testing condition so that linear regression analysis could be used to adjust the raw values to the mean cortical thickness of 3.3 mm. Specimens were restrained with custom made jigs (Figure 3-5). Six axial pullout tests (Instron, High Wycombe, UK) were performed per sample immediately after screw insertion, distracting at a strain rate seen in physiological conditions(Rubin and Lanyon, 1982) of 5 mm/min, recording at 20 Hz until the maximum force was demonstrated (using Bluehill software (Bluehill, Instron, High Wycombe, UK)).

Figure 3-5 - Mounted sample under testing in custom made jigs.

Statistical analyses were performed using IBM SPSS (Version 22, IBM, New York, USA), with significance accepted at $p \leq 0.05$. A one-way independent analysis of variance test (ANOVA) was used to examine differences in density between fresh bone types (humerus, ulna, femur and tibia). A two-way independent ANOVA was used to explore interactions in density between preparation types (R/O water for 48 hours, 2.4 M HCL for 24 hours and 2.4 M HCL for 48 hour) and bone types. Finally, a one-way independent ANOVA was used to examine differences in pull-out force between bone types. In cases where multiple comparisons were made within a given variable, a Bonferroni adjustment was made to prevent inflation of Type I error rate. The raw data is available online (Fletcher et al., 2018a).

Results

Comparison of different long bones and response to demineralisation

The initial analysis of the long bones showed no difference in mean volumetric bone mineral densities between all four types (Table 2).

Table 3-1 - Volumetric bone mineral density (vBMD) of four long bones and percentage reductions compared to fresh tibia. Results are reported as mean ± standard deviation

			24 hours 2.4 M HCl		48 hours 2.4 M HCl	
Bone Variant	Standard sample vBMD (gcm^{-3})	48 hr R/O vBMD (gcm^{-3})	vBMD (gcm^{-3})	% reduction from normal within each bone variant	vBMD (gcm^{-3})	% reduction from normal within each bone variant
Tibia	1.93 ± 0.08	2.01 ± 0.02	1.20 ± 0.04	38	1.16 ± 0.03	40
Femur	1.98 ± 0.09	1.99 ± 0.06	1.19 ± 0.08	40	1.18 ± 0.03	40
Humerus	1.96 ± 0.08	2.07 ± 0.04	1.18 ± 0.02	40	1.15 ± 0.01	41
Ulna	1.96 ± 0.07	1.93 ± 0.06	1.18 ± 0.05	40	1.15 ± 0.03	41
		($p>0.18$)				

Demineralising samples in 2.4 M HCl for 24 hours and 48 hours produced reductions in mean vBMD of 39% ($p<0.001$) and 41% ($p<0.001$) respectively. Whilst treatment for 48 hours reduced the density the most, post-hoc ANOVA showed this was not significantly more than the reduction at 24 hours ($p=0.159$). There were no significant differences in the percentage reduction in vBMD between the different long bones.

Table 3-2 - Raw and adjusted pullout forces and vBMD for different preparation and demineralisation techniques

	Density (gcm^{-3})	Mean cortical thickness (mm)	Pullout force (raw) (N)	Adjusted Pullout force for equivalent of 3.3 mm thick cortices (N)
Fresh Tibia	1.93 ± 0.08	3.37	920.7 ± 155.3	900.5 ± 103.7
Reverse Osmosis	1.85 ± 0.08	3.81	969.2 ± 231.2	839.7 ± 160.0
Phosphate Buffered Solution	1.87 ± 0.08	3.53	905.8 ± 190.6	847.1 ± 87.5
0.6 M HCl	1.44 ± 0.04	3.43	271.5 ± 175.0	260.7 ± 142.0
1.2 M HCl	1.35 ± 0.05	2.71	115.9 ± 29.6	142.4 ± 11.3
2.4 M HCl	1.19 ± 0.04	2.81	48.3 ± 12.4	56.7 ± 12.3
Dehydrated Tibia	1.66 ± 0.03	3.83	775.2 ± 250.5	667.9 ± 162.8
Reverse Osmosis Dehydrated	2.08 ± 0.04	3.74	595.9 ± 136.2	527.3 ± 124.7
Phosphate Buffered Solution Dehydrated	1.89 ± 0.11	4.24	1,082.0 ± 294.9	842.1 ± 245.5
0.6 M HCl Dehydrated	1.58 ± 0.06	2.86	434.2 ± 178.7	502.0 ± 101.6
1.2 M HCl Dehydrated	1.35 ± 0.07	3.11	114.3 ± 27.3	121.2 ± 12.0
2.4 M HCl Dehydrated	1.25 ± 0.06	2.19	41.6 ± 18.8	61.5 ± 21.8

Results from further testing on the tibial samples (Table 3) showed that demineralisation with 0.6 M and 1.2 M HCl also produced significant reductions in vBMD, with reductions of 25% and 30% respectively (both $p<0.001$). The different preparation conditions of for the tibial samples (R/O, PBS, fresh) did not generate significant differences in vBMD.

Dehydration of the samples produced varied results. There was a significant reduction in vBMD upon dehydrating the fresh tibia, 0.6 M and R/O samples (all $p<0.001$), but not with 1.2 M, 2.4 M and PBS samples (Table 4). Combining dehydration with demineralisation did not reduce the vBMD further than either method (demineralisation or dehydration) alone (Table 3-1).

Table 3-3 - Comparison of demineralised and dehydrated tibial volumetric bone mineral density (gcm^{-3}) (percentage reduction compared to fresh tibia)

	No demineralisation	0.6 M HCl	1.2 M HCl	2.4 M HCl
No dehydration	1.93 ± 0.08	1.44^{a} ± 0.04 (25%)	1.35^{a} ± 0.05 (30%)	1.19^{a} ± 0.04 (38%)
Dehydrated	1.66^{a} ± 0.03 (14%)	1.58^{ab} ± 0.06 (18%)	1.35^{a} ± 0.07 (30%)	1.25^{a} ± 0.06 (35%)

^{a} =different from Fresh tibia ($p<0.001$)

^{b} =different from undehydrated sample ($p<0.001$)

Pullout testing

The mean cortical thickness was 3.3 ± 0.6 mm. Equations linearly relating cortical thickness and pullout strength were generated for each test condition, using:

Equation 3-1

adjusted pullout force = raw pullout force + ((mean cortical thickness – test cortical thickness) x (adjustment coefficient))*

**Adjustment coefficient = pullout force / cortical thickness (different for each test condition)*

where the adjustment coefficient ranged between 17 for 2.4 M HCL and 273 for fresh tibia. Pullout forces were highest with fresh, R/O and PBS samples, with no significant difference between these (Table 3-2). Demineralisation caused significant decreases in pullout force for all acid concentrations, with the following respective mean percentage reductions: 0.6 M: 71%, 1.2 M: 84% and 2.4 M: 94%. Similar magnitudes of reductions were seen with the dehydrated samples compared to fresh samples, except for the 0.6 M samples: dehydrated tibia : 26%, 0.6 M : 44%, 1.2 M : 87% and 2.4 M : 93% (all dehydrated samples) (Table 3-3).

Discussion

Juvenile bovine long bones have bone mineral density and biomechanical properties that make them suitable for use in orthopaedic research. This research establishes, for the first time, this material as a suitable, novel model of normal and, following demineralisation, osteoporotic human bone that basic and applied research can utilise. The low variability demonstrated in bone density and pullout force, and the customisable potential of the model highlights the benefits over current models, with the added advantages from reduced ethical restrictions.

Comparable volumetric bone mineral densities (vBMD) were found amongst all four types of juvenile bovine long bone (humerus, ulna, femur and tibia), establishing that all untreated samples' vBMD are within the normal range of healthy human adult bone density (1.2-3.0 gcm^{-3}) (Hobatho et al., 1992, Cowin, 1989) and very closely match the findings from one study (adult male, cortical bone density ranging for femora from 1.85-1.93 gcm^{-3} and for tibiae 1.83-1.96 gcm^{-3}) (Evans, 1976). This ensures that, relating to this characteristic alone, juvenile bovine bone closely resembles normal human bone whilst demonstrating very low variability within and between all long bone types examined; especially compared to the variability seen within and between some human samples (Hobatho et al., 1992, Cowin, 1989). This may in part due to the animals being reared in identical conditions to each other; ensuring variations from both environmental factors remain minimised alongside similar baseline genetics. Additionally, several of these comparable animals will be slaughtered at the same age, providing an even more homogeneous sample set at time of procurement.

The objective of demineralisation is to reduce the vBMD to levels similar to those present in the target population. Indeed, all demineralisation concentrations (0.6 M, 1.2 M and 2.4 M) reduced vBMD, generating a spectrum of changes in bone density compared to fresh tibiae, with reductions of 25%, 30% and 38% respectively. Other studies using broadly similar acid demineralising techniques generated decreases in vBMD for 0.6 M HCl of 22% (Akbay et al., 2008) and 12% (Figueiredo et al., 2011), and for 1.2 M and 2.4 M, 28% and 44% (Figueiredo et al., 2011).

The reduction in pullout force seen with these demineralised models validates them biomechanically as the reductions seen are in keeping with loss of strength seen in osteoporotic bone. Additionally, these results are similar to previous research groups' findings using axial bovine skeleton; for 0.6 M HCl, the 71% decrease in pullout force seen for the 25% reduction in vBMD compares to 59% reduction in pullout force following a 22% reduction in areal BMD (Akbay et al., 2008).

The models created mimic the reductions in vBMD needed to successfully model osteoporotic bone with the three demineralisation concentrations creating a variety of densities. However, when creating models, the target bone density should be considered comparatively to the target population mean rather than arbitrary values for diseased bone. The World Health Organisation (WHO) defines osteoporosis as a bone density being 2.5

standard deviations below the mean (1994); thus establishing whether a bone density is osteoporotic is dependent on the population mean, which will vary between demographics. Further to this, more than 50% of “fragility fractures” (fractures that occur from standing height or less) do not occur in osteoporotic bone, but in osteopenic bone (1 to 2.5 SD below the population mean) (Unnanuntana et al., 2010), thus whilst the actual value of the vBMD is important, and quantitative definitions for osteopenia and osteoporosis are available(1994), it is the comparison between the normal population vBMD and the diseased model vBMD that is most important.

Demineralisation causes changes to bone properties by altering chemical composition and calcium content. This results in increased cortical porosity (Figueiredo et al., 2011), overall reduction in water content (though actually increased pore water content), loss of hardness, reduced compressive strength(Rho et al., 1998), decreased material stiffness and decreased toughness (McCalden et al., 1993, Egermann et al., 2005). In humans, cortical porosity increases with age and contributes to the detrimental properties seen in osteoporotic bone; it negatively correlates with bone strength (Macdonald et al., 2011) and increases bone fragility (McCalden et al., 1993). Untreated juvenile bovine bone has been shown to be more porous than mature bovine bone (Manilay et al., 2013). Further to this, whilst the general microstructure of cortical bovine bone is thought to be preserved despite demineralisation (Figueiredo et al., 2011), the process does lead to increased cortical porosity, reduced vBMD and reduced collagen content; affecting both the quantity and quality of the bone (Akbay et al., 2013) as per the aim of an osteoporotic model. Whilst the cortical porosity was not directly measured during this study, it has been shown that vBMD can be used as a surrogate for cortical porosity

(Rantalainen et al., 2011) and that changes in cortical porosity explain 76% of the changes seen in ultimate tensile strength (McCalden et al., 1993). The methods employed (using juvenile bone and demineralisation) are likely to have changed the pore sizes in manner representative of those seen in reduced density bone, given previous investigations of demineralisation (Figueiredo et al., 2011) and the reduction in tensile strength seen. In addition, the dimensions of the long bones and the sectioned samples ensures that the models share both macro and microscopic similarities to human bone.

It is known that the total water content of bone and its toughness decrease with age (Nyman et al., 2008, Jonsson et al., 1985) and that reduction in water content leads to a reduced fracture resistance (Nyman et al., 2013). Dehydration of bone samples stiffens collagen and stiffens bone overall (Nyman et al., 2006), however it is unclear exactly what happens to water distribution with bone aging (Nyman et al., 2006). Given the complicated distribution of water in bone, our simple method of drying samples did not refine the models further; whilst changes in vBMD and pullout forces were seen between dried and non-dried samples, these were generally neither significant nor consistent.

It has been noted by other research groups that these demineralisation techniques do not fully remove collagen so may represent osteomalacia more than osteoporosis (Akbay et al., 2008). Additionally, other parameters are yet to be assessed to validate fully these models, such as evaluating mineral to matrix ratios, water content, pore size, bone microstructure, hardness and toughness. Degradation methods similar to ours have been used by other research groups and have been shown to affect bone in the desired way, such as increasing pore size, however the lack of assessment of bone quality, beyond tensile testing, limits this study (Hernandez and van der Meulen, 2017). This may constrain the suitability of the model in mimicking all the conditions found in fracture fixations, however, despite the potential limitations of juvenile bovine bone, the reliability and low variability of the biomechanical properties, which do mimic those seen in osteoporotic bone, and the macroscopic dimensions are the key aspects needed for experimental biomechanical models to facilitate clinically relevant orthopaedic research. Further to this, our methods employed simple techniques for procurement, preparation and degradation, producing significant reductions in vBMD. Whilst routinely available safety equipment is required during demineralisation, no other special equipment is needed for the storage and disposal of specimens given that they can be treated as part of the food chain. No changes in the solutions more frequently than 24 hours are needed as there would only be negligible changes in acid bath concentration during demineralisation. Additionally, treatment for more than 24 hours caused no significant further reductions in vBMD between 24 and 48 hours; confirming previous findings (Lewandrowski et al., 1997, Lewandrowski et al., 1996). The strongest acid concentrations did significantly reduce the vBMD but in doing so macroscopically damaged the bone structure, creating very soft, malleable samples alongside reducing the cortical thickness from 3.3 mm (fresh tibia) to 2.8 mm (2.4 M HCl). These samples had very low maximum insertion torque levels (0.1 Nm) and very low pullout forces in biomechanical testing (~94% less than fresh samples). Given that the 0.6 M and 1.2 M solutions reduced vBMD without additional softening problems, we recommend using these concentrations for a reduced bone density model, though there may be further post demineralisation treatments that could be employed to stabilise the 2.4 M models.

Many studies that use pullout force to biomechanically validate models do not explicitly specify their testing methods, especially whether they controlled for the insertion torque applied. By adjusting for other variables such as cortical thickness and controlling variables such as the drill insertion angle and axial pullout angle, the vBMD validation will have been less affected by confounding factors. The insertion torque value of 0.5 Nm is within the range seen in human cortical bone (Ansell and Scales, 1968), and was found to be approximately 50% of the stripping torque for all specimens except for 1.2 M and 2.4 M samples. The pullout testing itself may not represent clinical screw failure methods accurately, as there is rarely a single catastrophic event in fixation failure. However, this method reduces confounders and is easily reproducible when assessing different preparation solutions, whilst being a testing method employed in many other studies.

Our model concentrates on cortical bone, both for simplicity and as cortical bone characteristics are far more significant in fracture mechanics and in dictating the fragility of bone; the trabecular bone contributes a trivial role to the biomechanical behaviours of bone (cancellous bone contributes <10% of bone strength (Holzer et al., 2009)). Indeed, it has been shown that when cortices are >1.5 mm, the cortical thickness alone significantly influences pullout strength independent of the trabecular bone (Seebeck et al., 2005). Further research into the validity of modelling longer bone sections plus research into the compressive strength and other biomechanical properties is warranted given the significant role this model could have in future advancements in biomechanics.

Ethical and financial constrains using juvenile bovine bone are minimal, especially compared to alternative animal and synthetic bone models. Comparative costs for a single, standard-sized in vitro tibial model compared to one juvenile bovine bone are as follows: normal density foam sawbone x16, osteoporotic sawbone x69, 4th generation sawbone x185(Sawbones Europe, 2016, Sawbones Europe, 2018) and cadaveric human tibia approximately x500 (Elfar et al., 2014). Furthermore, these prices do not reflect the significant associated costs with storage, shipping, use and disposal of human specimens, or the costs associated with creating in vivo models. Factoring in demineralisation materials, one reduced vBMD juvenile bovine tibia was generated for less than £5.

This study provides, for the first time, quantitative assessment of juvenile bovine long bones, and the effects of demineralisation on them. The similarities seen amongst the different long bones tested demonstrate that their vBMD would make them suitable for tests mimicking human bone. Given the macroscopic dimensions of juvenile bovine tibiae, that they are inexpensive, readily available, not subject to ethical limitations, demonstrates low variability and can be demineralised to modify their bone density, they can be utilised as a model for biomechanical and fracture fixation testing of both normal and reduced density bone conditions.

Competing Financial Interests Statement

The authors declare neither competing financial nor non-financial interests.

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3.4 Summary

This study establishes for the first time, the potential of juvenile bovine long bone as a surrogate for both normal and osteoporotic human specimens and offers preliminary validation for its use in biomechanical testing of fracture fixation screws. This offers a readily available, inexpensive, ethical source for a predictable, accurate model to be used in biomechanical research. Specifically, this study shows that this model can be used to enable appropriately powered biomechanical testing into the optimum tightness for screws – the theme of the next chapter.

The findings of how a lower bone density model could be made were very interesting but risked diluting the focus on the research question of improving screw fixation. I felt that adding in density reduction methods to the tightness testing would be introducing another variable, when the more important, simpler question of the impact of screw tightness in normal bone still had not been investigated.

Chapter 4 – Finding the optimum screw tightness using a bovine bone model

4.1 Context

When inserting screws, surgeons have two objectives: firstly, not exceeding the maximum torque of the screw hole and thus stripping the material around the threads and secondly, tightening a screw to gain the maximum compression and pullout force. Achieving these objectives relies on the surgeon’s subjective intraoperative assessment of the torque limits of the bone and of the optimum tightness for that screw. As shown in Chapter 2, the first objective is often failed with 1 in 4 screws stripping their screw holes. Despite the frequent use of screws in orthopaedics, the second objective of achieving the quantitative value of torque for optimum screw tightness has not been possible, as this value has not been known. Not knowing what tightness to target could be causative to screws being inserted poorly, being over tightened or stripped, and thus contributing to fixation failures.

When screws are using as mechanical fasteners in engineering, the knowledge of the shear limits of the homogenous material the screw is inserted into allows for quantitative values to be used to guide insertion. These values can be calculated prior to screw insertion. The factors contributing to the maximum tightness can be divided into fixed and variable. Fixed factors are the geometry of the screw, the density of the material receiving the screw (assuming it is homogeneous) and the coefficient of friction between the screw and the material. The variable factor is the depth of material engaged – the length of screw threads purchasing against the material. The hypothesis was generated that when using the same screw, the stripping torque could be calculated prior to insertion as the screw geometries would be known, alongside having accurate estimates of the bone density of the model based on the findings of Chapter 3, especially as the bovine model has very low inter and intra specimen bone density variability. So, if some samples were used to experimentally find the stripping torque, and these values were normalised based on the cortical thickness, then the main remaining variable - the coefficient of friction between the bone and the screw - could be deduced. Once all fixed variables were found, then the stripping torque could be calculated based on the cortical thickness of a screw hole, as this would be the only factor that would change the stripping torque. This would then allow many samples to be used, with different thicknesses to enable appropriate powering of tests to determine the optimum tightness.

4.2 Statement of Authorship

This declaration concerns the article entitled:

Non-locking screw insertion: No benefit seen if tightness exceeds 80% of the maximum torque.

Publication status (tick one)

Draft manuscript ☐ **Submitted** ☐ **In review** ☐ **Accepted** ☐ **Published** ☑

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Statement from Candidate	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature.

Signed		**Date**	07/08/2021

4.3 Study 3: Non-locking screw insertion: no benefit seen if tightness exceeds 80% of the maximum torque

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Abstract

Background

Millions of screws are manually tightened during surgery each year, but their insertion frequently results in overtightening and damage to the surrounding bone. We postulated that by calculating the torque limit of a screw hole, using bone and screw properties, the risk of overtightening during screw insertion could be reduced. Additionally, predicted maximum torque could be used to identify optimum screw torque, as a percentage of the maximum, based on applied compression and residual pullout strength.

Methods

Longitudinal cross-sections were taken from juvenile bovine tibial diaphyses, a validated surrogate of human bone, and 3.5 mm cortical non-locking screws were inserted. Fifty-four samples were used to define the association between stripping torque and cortical thickness. The relationship derived enabled prediction of insertion torques representing 40 to 100% of the theoretical stripping torque (T_{str}) for a further 170 samples. Screw-bone compression generated during insertion was measured, followed immediately by axial pullout testing.

Findings

Screw-bone compression increased linearly with applied torque up to 80% of T_{str} (R^2=0.752, p<0.001), but beyond this, no significant further compression was generated. After screw insertion, with all screw threads engaged, more tightening did not create any significant (R^2=0.000, p=0.498) increase in pullout strength.

Interpretation

Increasing screw tightness beyond 80% of the maximum did not increase screw-bone compression. Variations in torques below T_{str}, did not affect pullout forces of inserted screws. Further validation of these findings in human bone and creation of clinical guidelines based on this research approach should improve surgical outcomes and reduce operative costs.

Keywords: Insertion torque; fixation failure; tightness; compression; pullout force

Introduction

Screws are widely used in osteosynthesis to manipulate and stabilise bone fragments. Surprisingly, there is a lack of quantitative assessment in the literature of the best methods for tightening screws in bone. Indeed, once all screw threads are engaged, the benefits of further tightening are unclear in terms of generated axial forces, both compressive and tensile. Screw insertion for osteosynthesis is predominately performed under subjective control and often imperfectly, with stripping of the surrounding bone occurring with 1 in 4 screws in biomechanical testing (Fletcher et al., 2020d). This implies a lack of awareness of the shear limits of bone and/or an inability of surgeons to predict or perceive them. The main consequence of stripping the surrounding bone, occurring when the applied torque exceeds the maximum shear that can be tolerated (stripping torque (T_{str})), is a reduction in pullout strength of over 80% (Collinge et al., 2006, Wall et al., 2010). This may contribute to fixation failures, especially given how stripped screws lead to fibrous healing around the screws, rather than initial new bone formation (Togni et al., 2011) and fixation issues can contribute to overall failure (Broderick et al., 2013). The sub-maximal tightness that generates the optimum construct, as functions of maximal compressive and pullout forces, is currently unknown. Some studies have found that increasing screw tightness up to T_{str} generates increased pullout strength (Troughton, 2008, Tsuji et al., 2013, Edwards et al., 2005), yet other studies do not support this conclusion (Cleek et al., 2007, Ricci et al., 2010, Lawson and Brems, 2001). The surgical techniques used to tighten screws have been shown to be highly variable (Feroz Dinah et al., 2011, Stoesz et al., 2014, Gustafson et al., 2016), leading to millions of loose screws being inserted intraoperatively worldwide each year. Whilst screw tightness as a percentage of the maximum possible varies greatly between surgeons, 86% has been suggested to be the average of what is clinically applied (Cordey et al., 1980). However, even if this value is representative of current clinically applied torque, there is no evidence to justify targeting or achieving this figure in terms of creating the optimal construct. Equally, there is no adopted clinical method for predicting this value before screw insertion, hence the flawed technique of subjectively tightening screws continues.

Comparisons between insertion torque and cortical thickness have been performed, with Gotzen et al. (1976) finding a correlation of (r = 0.95) (Gotzen, 1976), and Lawson and Brems (2001) reporting a qualitative correlation (Lawson and Brems, 2001). Cordey et al. (1980) found that cortical thickness did correlate significantly with stripping force for human tibiae (r = 0.78), but not significantly for human femora (r = 0.48). Equations have been used to predict pullout strength for cylindrical and conical screw designs, finding that with the former design the prediction correlated at $R^2 = 0.93$ when using an integral formula based on screw geometries and bone mechanical properties (Tsai et al., 2009). Furthermore, similar equations can be used to predict the stripping limit of homogeneous materials (Troughton, 2008, Zdero et al., 2017a). These methods are based on the screw geometry and material properties of the sample receiving the screw, and have been used to confirm stripping values retrospectively in human and artificial bone (Aziz et al., 2014). However, these equations have not been applied predictively to screw fixation in part because of the heterogeneous properties of bone and the intraoperative variability of the depth, direction and shape of screw holes (Messmer et al., 2007). Additionally, they have not been used to address what the optimum torque might be.

This study primarily aimed to assess whether stripping torques can be predicted using cortical thickness and/or an equation based on screw and bone properties, and secondly, to identify if there is a value or range for optimum screw tightness as functions of screw compression and pullout force.

Methods

Predicting the stripping torque

Eight tibial diaphyses from four, 4-5 month old juvenile cows, were obtained from a commercial butcher (Bartlett and Sons, Bath, UK) and used within the animal welfare regulations and guidelines. This bovine bone model has been previously validated as an adequate surrogate of normal density bone, whilst providing reduced variability compared to human models (Fletcher et al., 2018b, Fletcher et al., 2018a). All soft tissues were physically removed, before cutting each bone into 20 mm length cross sections, giving six samples per tibiae. Any residual trabecular bone was removed. Samples were stored in phosphate buffered solution-soaked swabs at -20°C and defrosted for 18 hours before use. Each section had 2.5 mm pilot holes drilled perpendicularly using an automated bench drill with the holes spaced equally around the circumference, at least 18 mm apart (ASTM, 2017). The mean average cortical thickness of each hole was calculated by measuring the cortical thickness once from both sides of the sample with digital Vernier's callipers.

Establishing the relationship between stripping torque and a predictive equation

Self-tapping, fully threaded, non-locking 3.5 mm cortical screws (Stryker, Newbury, UK) were inserted by hand, through a washer into 54 unicortical holes using a torque measuring wrench (DTL-100i Digital Torque Wrench, Checkaline Europe Ltd, Birmingham, UK). Torque moments were recorded until the stripping torque (T_{str}) was achieved when the bone stripped around the screw. The relationship between cortical thickness and T_{str} was evaluated, using linear regression analysis. Next, a predictive equation (Troughton, 2008) was tested for its ability to calculate the stripping torque (Equation 4-1).

Equation 4-1

$$T_{str} = \frac{TYS}{\sqrt{3}} \pi \cdot D_p \cdot L \cdot r \cdot \frac{p+2f\cdot r}{2r-f\cdot p}$$

Where TYS= tensile yield stress, D_p = pitch diameter, L = axial length of full thread engagement, r = pitch radius of screw, p = reciprocal of threads per unit length, f = coefficient of friction of the bone-screw interface.

To use this equation, the coefficient of friction between the screw and the bone, and the tensile yield stress of the material need to be calculated. These unknown variables were found using nonlinear, least-squares data fitting in Matlab (v2018b, The MathWorks Inc., Natick, MA, USA). Following this, validation of Equation 2 was performed by using half of the experimental stripping values to recalculate the unknown variables, followed by using Equation 2 to predict the stripping values for the other 27 samples. To find the optimal values, initial conditions for the coefficient of friction and tensile yield stress were set to 0.4 (Parekh et al., 2013, Zdero et al., 2017b), and 90 MPa (Cowin, 1989, Parekh et al., 2013, Zdero et al., 2017b, Bayraktar and Keaveny, 2004), respectively. Regions of search were bound between 0 and 1 for *f* and between 1 and 120 MPa for *TYS*.

Measuring the effect of different percentages of the stripping torque as functions of compression and screw pullout.

To investigate optimum torque, 170 bovine samples were prepared in an identical manner as described above. Custom jigs were used to mount specimens on a materials testing machine (Instron 5967, Instron, High Wycombe, UK) (Figure 4-1). The same 3.5 mm screws were inserted unicortically by hand through a washer, until at least 2 mm of screw threads protruded from the inner cortex. At least 8 mm of screw threads were left exposed on the near cortex to enable placement onto slotted jigs attached to a 5 kN load cell mounted on the material test machine crosshead (Figure 4-2). Using cortical thickness of the hole, Equation 2 was used to predict the T_{str}. Using this value to indicate 100% tightness, six decile target tightness groups were chosen - 40-49%, 50-59%, 60-69%, 70-79%, 80-89% and 90-100% - and the required torque values for each insertion were calculated. This method was performed 170 times with random allocation of each test into a decile group, ensuring at least 25 samples were tested per group. Whilst recording at 20 Hz using data acquisition software (Bluehill 3, Instron, High Wycombe, UK), screws were tightened to the targeted torque using the same digital torque wrench as previously. During insertion, the compression force and applied torque were recorded simultaneously. Upon reaching the target tightness, the final compression generated was recorded and axial pullout was immediately performed at 5 mm/min (Inceoglu et al., 2004, ASTM, 2017), until the maximum pullout force was achieved and/or free displacement of the screw occurred. To standardise for variations in cortical thickness, forces generated were normalised per mm of cortical thickness (Aziz et al., 2014).

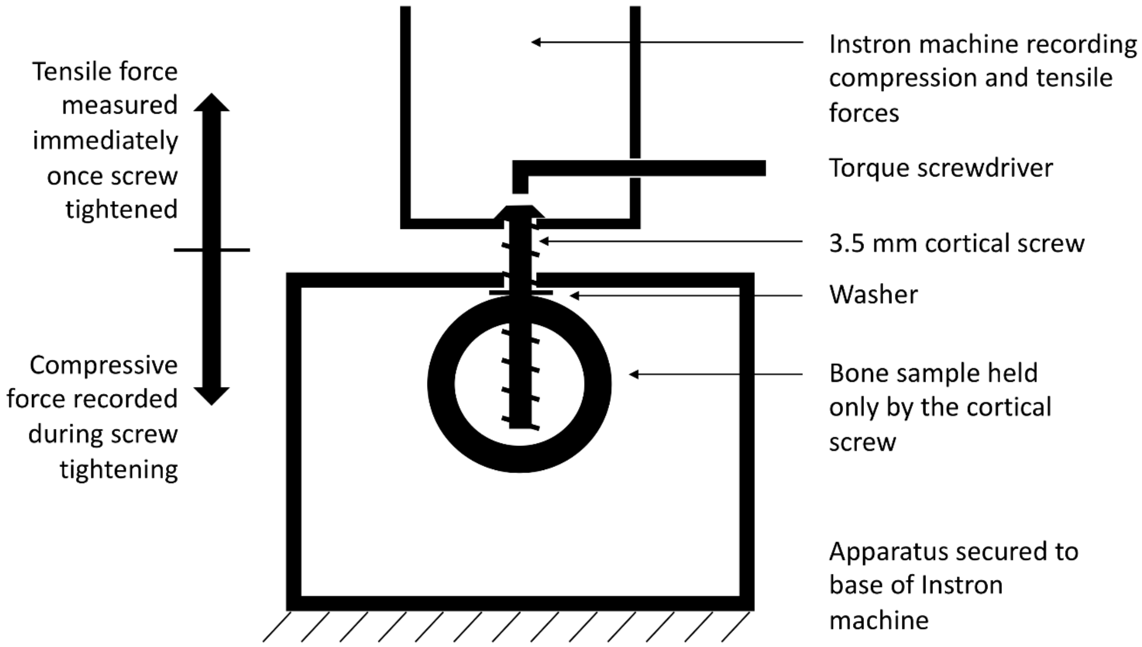

Figure 4-1 - Testing apparatus to continuously record compression whilst applying increasing tightness using a torque wrench, followed by immediate axial pullout.

Statistical analysis was performed using a linear regression model to test for an overall effect of cortical thickness (independent variable) on experimental stripping torque (dependent variable), of experimental stripping torque on predicted stripping torque, of screw tightness on pullout force and compression force, and of cortical thickness on raw pullout force. The adjusted R^2 values and the p-values of the F-test were used to indicate how well the model fit the data. For compression forces, we analysed the impact of increasing screw tightness in more detail: we grouped tightness in 10%-blocks and ran a pairwise comparisons between every two of the tightness groups using a two-sided t-test with unequal variances. We adjusted the p-values for multiple testing using Benjamini, Hochberg, and Yekutieli control of the false discovery rate. Results for all statistical analysis were considered significant at an alpha of 0.05. All statistical tests were performed with ‘R’ software, v3.3.3 (R: A language and environment for statistical computing. R Foundation for Statistical Computing). Data is freely available via an online data repository.

Results

Cortical thickness demonstrated a linear relationship with experimental stripping torque; $R^2 = 0.869$, $P<0.001$ (Figure 4-2). Non-linear optimisation generated a coefficient of friction for the bone-screw interface of 0.336 and a tensile yield stress of 75.67 MPa. Comparing the predicted stripping torque, using Equation 4-1, to the experimental stripping torque generated an $R^2 = 0.881$, $P<0.001$ (Figure 4-3). The non-linear optimisation based on half of the initial samples (n=27) found a coefficient of friction of 0.337 and a tensile yield stress of 75.87 MPa, with compared to Equation 4-1 predictive stripping torque showing a relationship of $R^2=0.830$, $P<0.001$.

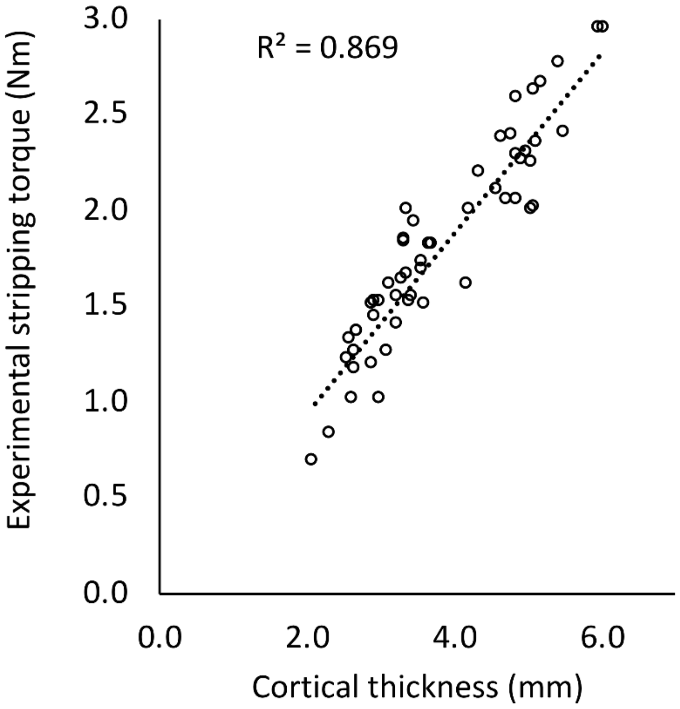

Figure 4-2 - The relationship between experimental stripping torque and cortical thickness for 54 juvenile bovine samples.

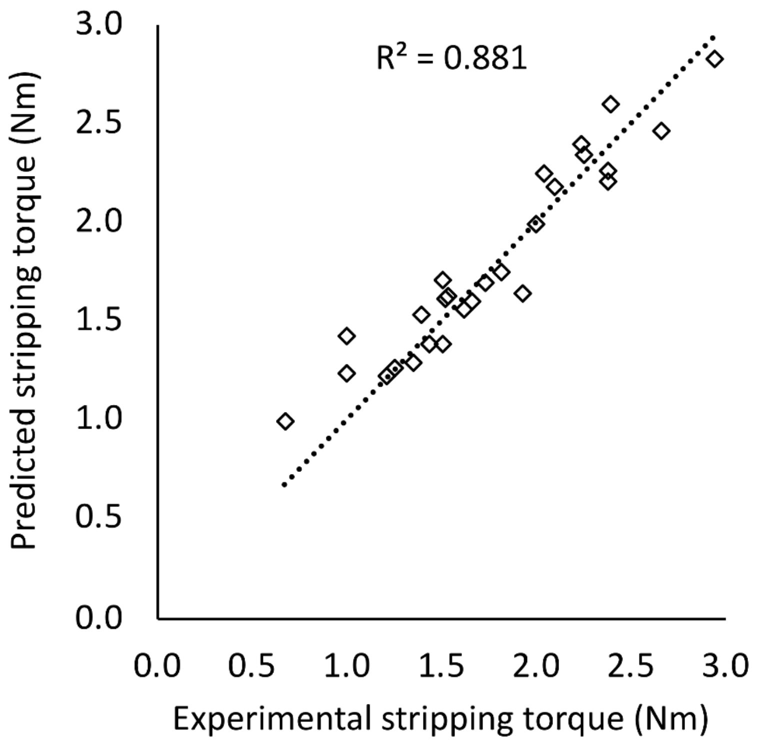

Figure 4-3 - The relationship between predicted stripping torque calculated using Equation 1 and the experimental stripping torque for 27 samples.

Seven samples were detected to have been inadvertently stripped during insertion, where peak torque occurred before the targeted experimental torque was achieved; these data were excluded from analysis. Statistical analysis was performed for the remaining 163 samples. Using the continuous measurements of compression as more torque was applied (n=509), as screw tightness increased from seating torque (where the screw head first exerts compression) to 80% of the maximum torque, compression increased in a linear fashion ($R^2 = 0.752$, $P<0.001$). Grouping the samples based on their final tightness decile groups, further increases in tightness from 70 to 79%, to 80 to 89% and to 90 to 100% did not generate any significant increase in compression (P=0.22 and 0.14 respectively) (Figure 13).

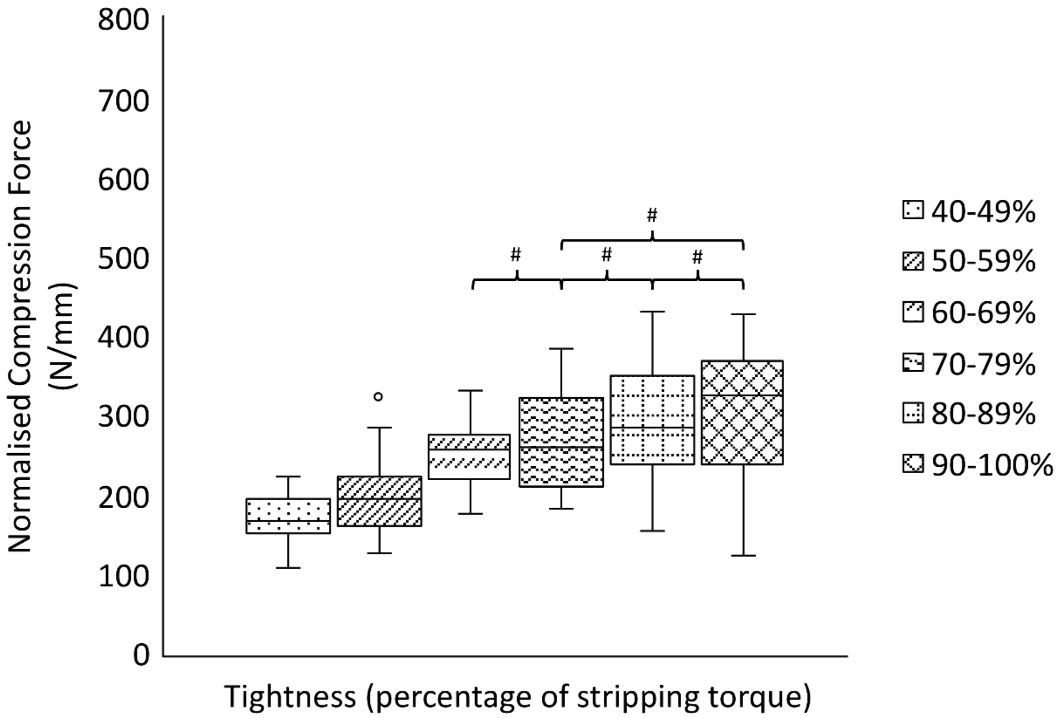

Figure 4-4 - Box and whisker plot of normalised compression force (N/mm) in decile groupings as functions of screw tightness (as a percentage of the stripping torque) (n=163). Boxes indicate interquartile range, with a median line. Whiskers indicate maximum and minimum range. $^{\#}$ indicates the non-statistically significant comparisons; P>0.05.

No significant difference in the normalised pullout force was found as tightness increased between 40 and 100% of T_{str} (R^2 = 0.000, P=0.498) (Figure 4-4). Cortical thickness was found to be predictive of raw pullout force (R^2 = 0.484, P<0.001).

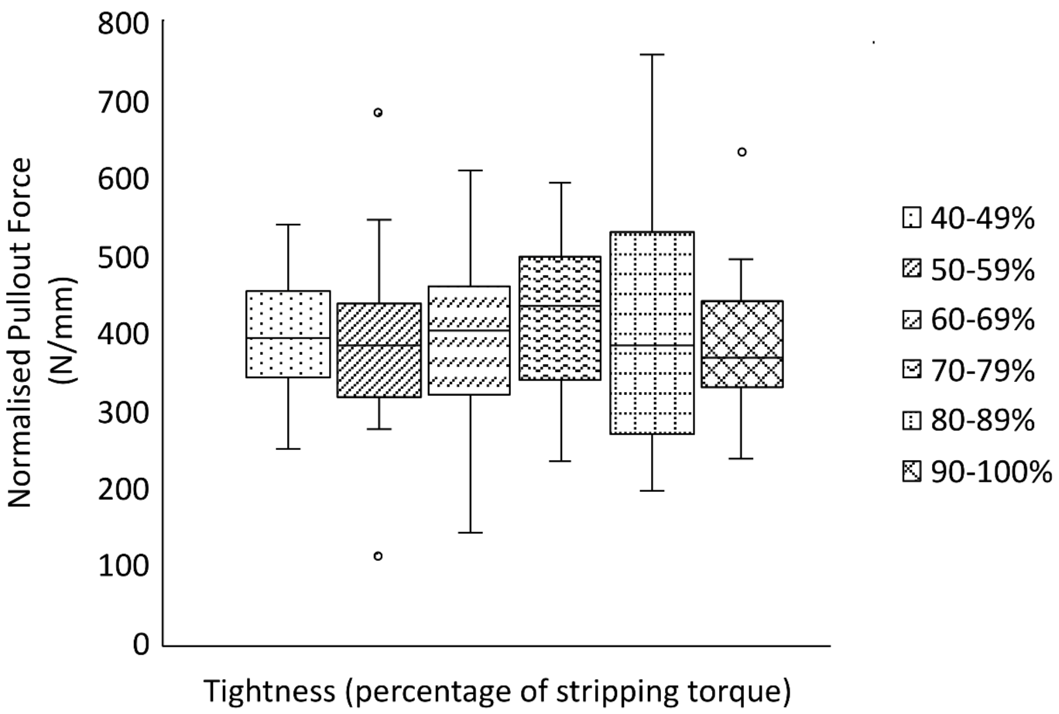

Figure 4-5 - Box and whisker plot of normalised pullout force (N/mm) in decile groupings as functions of screw tightness (as a percentage of the stripping torque) (n=163). Boxes indicate interquartile range, with median line. Whiskers indicate maximum and minimum range. All comparisons between decile groups were not significant; P>0.05.

Discussion

Identifying the stripping limits of bone samples, using predictions based on cortical thickness, enables calculation of the specific tightness targets. Using the methods described establishes a foundation for developing techniques to improve screw insertion, making screw use more effective. Additionally, discovering a value that beyond which no construct benefits as functions of compression and pullout forces are generated – which was found between 70 and 80% of the stripping torque – provides surgeons with an evidence-based tightness to target.

Increasing tightness generates greater friction between the screw and the interthread bone. As the screw head prevents further penetration of the screw through the cortical bone, more rotation exhibits a tensile force on the bone, based on the resultant force and the coefficient of friction at the bone-screw interface. It has previously been shown experimentally that the compression force generated during tightening is directly proportional to the amount of torque applied (Perren et al., 2000, Ricci et al., 2010). This is seen within this study with the initially linear relationship between compression and increasing tightness; however, beyond 80% of the maximum torque, no further benefits were seen, which we speculate to be explained by increasing frictional forces becoming balanced by increasing plastic deformation occurring around the screw threads. Extra motion from a less stable construct may have benefits as more motion at the fracture site may stimulate greater bone healing. However, reduced screw purchase may generate micromotion at the bone/screw interface, leading to the creation of fibrous tissue rather than neobone formation (Wallace et al., 1994, Kenwright et al., 1986). Further to this, the damage caused in stripping bone around screw threads may impact on the healing potential of the fracture site (Cleek et al., 2007).

Pullout force did not vary as a function of tightness. We postulate that during screw insertion, a tensile force is applied to the material between the threads. This causes failure independent of the failure mechanism seen during screw pullout, so long as the maximum stripping torque has not been reached during insertion. If stripping occurs, this disconnects the bone between the screw threads and that surrounding the screw, considerably reducing the overall construct's ability to resist axial force. However, if the maximum insertion torque is not exceeded during insertion, the interaction between the screw threads and the bone does not affect the force that can be applied to the construct as a whole; the pullout force of a screw is determined by the deformation at the boundary of the outer threads and the bone, not by changes in the bone within the threads. This is seen with the failure mechanism that occurs during pullout being shearing of the material at the edge of the outer diameter of the screw, evidenced with the ‘corkscrew’ of material that often remains within the screw threads following pullout testing; also observed by others (Cleek et al., 2007). Given that variations in screw tightness only effect compression (torques below T_{str} being found to not affect pullout force), optimum tightness as functions of compression and pullout force can be defined purely on its effect on the former - approximately 70 to 80% of the T_{str}. Although in vitro pullout strength may not change with tightness when tested immediately, there may be ramifications in vivo from excessive torque in terms of compromised bone remodelling from any damage caused from overtightening. Furthermore, as there do not appear to be benefits of tightening screws closer to the manually undetectable, irreversible stripping torque, tightening screws to the levels seen in some biomechanical papers seems unwise (Fletcher et al., 2020d).

A frequently quoted, although historic, paper by Cordey et al. (1980) reports that surgeons tighten screws to 84% (SD 13) of the maximum torque in cadaveric tibiae and 88% (SD 18) in cadaveric femora; averaged to 86% (Cordey et al., 1980). However, generalising this paper to describe what is clinically achieved is flawed, as the value was generated by asking surgeons (both orthopaedic and general surgeons) to tighten only one 4.5 mm screw into cadaveric tibiae (n=63) and femora (n=35); using this figure to describe other situations should be performed cautiously, if at all. Collating data from the literature on achieved screw tightness has shown values of 78% (SD 10) for cortical (n=1,079) and 80% (SD 6) for cancellous screw insertions (n=431) (Fletcher et al., 2020d). However, what surgeons subjectively achieve and what is optimal for constructs may well be different, as shown by our data. One of the key improvements in this research compared to previous studies is the control of the insertion torque including not using subjective measurements such as surgeon’s predictions. Subjective feel related to applied torque is highly variable (Fletcher et al., 2020d), however insertion torques are almost always not mentioned in biomechanical studies. This study highlights that when testing screw/bone interactions, especially when variations in compression may alter outcomes, the tightness of screws needs to be measured. In part, to ensure that screws have not stripped the material on insertion, but also as the occurrence of stripping is poorly detected by surgeons (Stoesz et al., 2014).

Previous studies comparing compression and applied torque have reported a directly proportional relationship (Egol et al., 2004a, Ricci et al., 2010, Perren et al., 2000, Cordey et al., 1980), which appears to only be correct up to 80% of the stripping torque. However, no studies have quantitively assessed optimum tightness as functions of compression and pullout force. Cleek et al. (2007) measured pullout force for screws inserted to 50%, 70% and 90% of the maximum (the maximum being determined by the stripping torque of a contralateral ovine tibiae hole), with the preload (compression) being removed before pullout testing (Cleek et al., 2007). In their study, where 3.5 mm screws were inserted into 2.7 mm pilot holes using a washer, they described qualitatively that the compression generated linearly correlated with the applied torque in the initial tightening, before non-linearly increasing. Regarding pullout force, they reported that there was no difference for screws tightened between 50% and 90% of the maximum tightness, nor between 50% and 70%, but that there was a difference between 70% and 90% ($P<0.05$). Whilst they followed the manufacturer’s recommendation, common practice involves inserting 3.5 mm screws into 2.5 mm pilot holes (unless using cannulated screws, which these were not stated as being), thus their pilot holes are likely to have affected their results (Battula et al., 2008). Of their tests to determine the failure torque, 33% had to be discarded for methodological reasons resulting in only 20 samples being available for analysis and, whilst the targeted percentages cover a spectrum of those seen, only three discrete values were tested.

Lawson and Brems (2001) compared screws inserted to 10%, 50%, 90% of the maximum torque and one group of screws inserted to >100% of the maximum. Using juvenile ovine femora, they found a difference between the stripped samples and the others, but no significant difference in the maximum pullout force between any non-stripped groups. In further tests, they stated that unicortical and lag screws should not be inserted beyond 65% of the maximum, though tests were only performed at ~10% and ~68% of the maximum torque, and with stripped samples. Cleek et al. (2007) reported that they did not find a reduction in the pullout force of that found by Lawson and Brems because they released the compression generated prior to axial pullout testing. However, this explanation is unclear, as we found that so long as the compression force is less than the pullout force generated, it can be ignored when interpreting the pullout; as failure occurs by shearing the bone at the extremities of the screw threads, rather than between them.

There are limitations with the methods utilised in this study. The relationship between tightness and force is based on theoretical calculations of the insertion torque as a percentage of the stripping torque. Firstly, it is based on perfect insertion of all screw threads into an isotropic homogeneous material, and secondly, given variations in both the samples and the accuracy of measuring cortical thickness, a targeted percentage may be different to the actual torque required for that percentage. Indeed, seven samples (4%) were stripped on insertion when a predicted torque value below 100% transpired to be experimentally above it.

Using an in-vitro bovine model reduces specimen variability, especially compared to using human bone (Fletcher et al., 2018b), whilst demonstrating similar properties to human bone (Hobatho et al., 1992, Cowin, 1989, Evans, 1976, Swartz et al., 1991)).

Furthermore, it offers lower variability and less ethical and financial restrictions to other testing models and an increase in power for the same effect size compared to alternative methods used in papers with similar aims (Cleek et al., 2007, Aziz et al., 2014, Lawson and Brems, 2001). However, the findings may not represent the behaviours occurring with in-vivo human bone. In vivo insertion torques have been found to be higher than in vitro torques, for example with spinal pedicle screws (Buhler et al., 1998), though we postulate that the trends found should still be the same, even if the raw values are not.

Unicortical insertion was performed to reduce the number of animal specimens needed, and because bicortical insertion would have considerably reduced the chance of both cortices being engaged perpendicularly, given the shape of the tibial diaphyses. Lawson and Brems (2001) found that for axial pullout, it is the total cortical thickness that linearly correlates with the stripping torque, rather than whether the cortical thickness is generated from one or two cortices (Lawson and Brems, 2001). However, the findings from unicortical situations within this study may not be generalisable to bicortical fixation. Washers were used to model plates pressing against the periosteum, which may explain some of the differences in the results between this study and others assessing maximum pullout force; pullout capacity may be overestimated if there is a higher concentration of load more distally due to a lack of proximal restraint (MacLeod et al., 2015).

Whilst a very common testing method, axial pullout testing is not necessarily an appropriate model of in vivo screw failure, which is typically through progressive loosening rather than a single episode of catastrophic failure. However, this testing method is recognised as a standardisable way of controlling variables (ASTM, 2017), and ensures that trends can be seen, and comparisons made, even if the raw values are not fully representative. Furthermore, the failure rate was rapid, and did not allow for stress relaxation to occur following screw insertion. Though this may have elevated the raw values of the forces seen, the trends should remain the same (Inceoglu et al., 2004).

Conclusion

Non-locking screws should be tightened to between 70% and 80% of the maximum torque. As pullout force does not change with screw tightness once all threads are engaged, insertion should be optimised for compression. More tightness, once the screw head is seated, was not found to generate more pullout force. Establishing optimum tightness for screws in fracture fixation will reduce failure rates especially given the current incidence of overtightened screws. Further work is needed to corroborate these findings in human bone, alongside development of methods for predicting stripping limits in bone pre and/or intraoperatively.

Conflict of interest and sources of funding

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4.4 Summary

This chapter investigated the use of an engineering calculation for stripping torque and showed that it could be used to predict experimental stripping torques in bone and thus be used to calculate different percentages of the stripping torque. It was found that the compression generated increases with increased tightness, but only to 80% of the maximum, beyond which there were no benefits. There was no gain in pullout strength with further tightening, meaning that an optimum tightness can be suggested at 70-80% of the stripping torque.

This is big step forward in improving screw fixation. Not only had a pivot point beyond which no further benefit in more tightness was found, a method for calculating this prior to screw insertion had been tested and shown to work well. Firstly, this meant that as the methodology had been proved, these findings could be validated in human bone – no human samples would need to be potentially wasted in establishing a method. Secondly, as there appeared to be an optimum tightness for screw tightness as a function of compression, any research studies looking at screw compression that did not control for insertion torque might be flawed. Equally, any screw insertion studies that did not measure screw insertion torque might be limited as they may not have detected when screws had stripped the screw hole on insertion. The stripped insertions had considerable reductions in pullout strength, which if occurring undetected in other studies would be resulting in weaken and destabilise constructs, likely impacting on their results.

Already these findings have implications for current practice. Whilst idealised, and potentially not practical (at least with current technology) this study showed that by measuring the variables for screw insertion it allowed for accurate prediction of the stripping torque and thus calculation of the optimum tightness. The geometry of a screw can be measured or found from industry literature, though the cortical thickness and bone density are harder to measure. However, these latter two can still be estimated, perhaps by using a depth gauge on one cortex and doubling for the cortical thickness, and by using population averages for bone density in the operative region of the injury. Even the mechanism of injury can help gauge what the bone density of the individual is likely to be based on the energy required to cause the fracture, i.e. a fall from standing height compared to a vehicle collision. An alternative method would be to measure the torque being applied to screw during insertion. If any were stripped, then that torque value could be used to at least calibrate the maximum torque for further screw holes to help prevent further stripping.

Other potential consequences from these findings could be considered. If screws were inserted to their optimum torque, and especially if they were not stripped on insertion, it should mean that the time needed for insertion would be reduced, if only because screw errors would be reduced as would be the frequency of needing to change screws. There might currently be a safety factor built into recommended fixation techniques such as needing three bicortical screws either side of a fracture. Potentially if all screws were inserted to their optimum tightness either fewer screws might achieve the same stability or the same number of correctly inserted screws might allow more stability and thus more patient mobility such as increased / earlier weight bearing – a factor that is key in certain patient populations where reduced weight bearing is either hard to achieve or detrimental to a patient’s overall well-being.

Chapter 5 – Finding the optimum tightness for non-locking screws in human bone models

5.1 Context

With the establishment of the methodology for testing different screw tightness, validation was needed in human bone models. With the increased value of human bone samples (ethically and financially), less samples were available than previously used for the bovine bone study, however the previous work had demonstrated that the methodology was robust. Human testing was needed to improve clinical transferability of bovine testing results. It would also add further confirmation to the theory of being able to use predictions of the maximum screw tightness to aid in targeting an optimum and confirm whether there is an optimum tightness in human bone.

5.2 Statement of Authorship

This declaration concerns the article entitled:			
Stripping torques in human bone can be reliably predicted prior to screw insertion with optimum tightness being found between 70% and 80% of the maximum.			
Publication status (tick one) **Draft manuscript** ☐ **Submitted** ☐ **In review** ☐ **Accepted** ☐ **Published** ☑			
Publication details (reference)	Fletcher et al., Stripping torques in human bone can be reliably predicted prior to screw insertion with optimum tightness being found between 70% and 80% of the maximum. Bone & Joint Research 2020:9(8), 493-500		
Copyright status (tick the appropriate statement)			
I hold the copyright for this material ☑	Copyright is retained by the publisher, but I have been given permission to replicate the material here ☐		
Candidate's contribution to the paper (provide details, and also indicate as a percentage)	The candidate contributed to / considerably contributed to / predominantly executed the… Formulation of ideas: 80% Design of methodology: 80% Experimental work: 80% Presentation of data in journal format: 90%		
Statement from Candidate	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature.		
Signed		**Date**	07/08/2021

5.3 Study 4: Stripping torques in human bone can be reliably predicted prior to screw insertion with optimum tightness being found between 70% and 80% of the maximum

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Abstract

Aims

To devise a method to quantify and optimise tightness when inserting cortical screws, based on bone characterisation and screw geometry.

Methods

Cortical human diaphyseal tibiae screw holes (n=20) underwent destructive testing to firstly establish the relationship between cortical thickness and experimental stripping torque (T_{str}) and secondly to calibrate an equation to predict T_{str}. Using the equation's predictions, 3.5 mm screws were inserted (n=66) to targeted torques representing 40-100% of T_{str}, with the compression generated during tightening recorded. Once the target torque had been achieved, immediate pullout testing was performed.

Results

Cortical thickness predicted the stripping torque (R^2=0.862, P<0.001) as did an equation based on tensile yield stress, bone-screw friction coefficient and screw geometries (R^2=0.894, P<0.001). Compression increased with screw tightness up to 80% of the maximum (R^2=0.495, P<0.001). Beyond 80%, further tightening generated no increase in compression. Pullout force did not change with variations in submaximal tightness beyond 40% of T_{str} (R^2=0.014, P=0.175).

Conclusion

Screws tightened to between 70 and 80% of the predicted maximum generated optimum compression and pullout forces. Further tightening did not significantly increase compression, made no difference to pullout and increased the risk of the screw holes being stripped. Whilst further work is needed developing intraoperative methods for accurately and reliably predicting the maximum tightness for a screw, this work justifies ensuring insertion torque is considerably below the maximum.

Key words: Screw fixation, torque, stripping, optimum tightness, non-locking screw

Article Summary

Article focus:

- To find the optimum tightness for non-locking screw tightness as a percentage of the stripping torque as a function of compression and pullout force

Key messages:

- Bone characteristics and screw geometries can be used to predict the maximum torque for a screw hole in human bone prior to insertion, with between 70 and 80% of the maximum torque providing the optimum screw tightness.
- Having a targetable torque for screw insertion should reduce rates of screw stripping and improve fixation constructs.
- Stripping screw holes reduces pullout force and compression by more than 90%.

Strengths and limitations:

- Automated screw insertion ensured that surgical technique was removed as a confounder

- In vitro testing on diaphyseal cortical fixation - results need validation in other bone regions
- Methods used are only an assessment of the immediately implantation consequences and offer no assessment of healing effects, or of changes in constructs as stress dissipates over time and under loading

Introduction

Non-locking screws continue to play a crucial role in the operative management of the more than nine million fractures estimated to occur worldwide each year (Johnell and Kanis, 2006). However, the insertion of screws by surgeons is subjectively controlled and frequently suboptimal; biomechanical evaluations of screw insertion commonly show overtightening or stripping of the surrounding bone (Fletcher et al., 2020d). When screw holes are stripped, the fixation strength is greatly reduced, and this lack of awareness of the torsional limits in the bone, and/or the inability to detect them by surgeons, contributes to fixation failures (Broderick et al., 2013). If stripping occurs and is detected, larger screws can be used in the same hole in an attempt to rescue the situation, though this can have limited success (Wall et al., 2010). Alternatively, screws might have to be sited elsewhere, leaving the empty, stripped screw hole to act as a stress riser(Brooks et al., 1970). Operative time and implant wastage both increase when screws are inserted poorly (Andreassen et al., 2004). As stripping torques are manually unpredictable and excessive torques result in irreversible construct damage (Fletcher et al., 2019, Wall et al., 2010), to reduce the chance of stripping occurring, the optimum and maximum torques for a screw hole would ideally be known for a chosen screw prior to its insertion. Additionally, knowing the optimum torque to target could potentially lead to better outcomes due to more robust constructs being created, that are able to offer more compression and greater resistance to failure during loading.

There is currently a scarcity of research into methods for creating optimum fixations in human bone, with data available only from bovine models and no known tightness to target in human bone. In bovine bone, screw tightness greater than 80% of the stripping torque (T_{str}) offers no further benefits to fixation, in terms of compression generated or pullout force resisted, and rather increases the risk of stripping the bone(Fletcher et al., 2019). Methods for predicting the T_{str} have been investigated such as using the torque required to advance a screw during insertion, before the screw head contacts the plate or bone – the plateau torque (T_{plat}). This has shown during automated insertion to be a strong predictor for the T_{str} for cancellous human bone; $R^2 = 0.84$, ($n=80$, $p<0.001$) (Reynolds et al., 2013).

The aim of this study was to quantify and optimise tightness for the insertion of cortical fracture-fixation screws, based on bone characterisation and screw geometry. We hypothesised that submaximal torques would generate the optimum constructs as a function of compression and pullout force, and that these methods could provide justification for targeting a safe range of torques that reduce the risk of bone stripping.

Methods

Cortical bone rings were made from the diaphysis of a single human cadaveric tibia (female, age 78, body mass index 24) by longitudinal sectioning into 15 rings. This was procured under local ethical approval and stored in vacuum packaging at -20ºC in the institutional tissue bank, being defrosted for 18 hours prior to use. All soft tissues were removed alongside all cancellous bone from the medullary cavity of the rings. Each ring had pilot holes of 2.5 mm diameter drilled perpendicularly to the bone surface using an automated bench drill. Pilot holes were spaced approximately 18 mm apart (ASTM, 2017), with drill bits changed after 20 holes, with a total of 86 holes created. The cortical thickness at the site of each pilot hole was measured with digital Vernier's callipers from both the proximal and distal aspects, with the average value recorded.

Establishing experimental stripping torque

Equation 5-1 (Troughton, 2008) predicts the stripping torque (T_{str}) of a homogeneous sample based on the material properties and screw geometries. To employ this equation, it first required identification of the unknown material variables (cortical thickness, tensile yield stress and the coefficient of friction between screw and bone).

Equation 5-1

$$T_{str} = \frac{TYS}{\sqrt{3}} \pi \cdot D_p \cdot L \cdot r \cdot \frac{p + 2f \cdot r}{2r - f \cdot p}$$

Where TYS= tensile yield stress, D_p = pitch diameter, L = axial length of full thread engagement, r = pitch radius of screw, p = reciprocal of threads per unit length, f = coefficient of friction between the screw and bone.

The screw geometries remained the same throughout the calculations, as identical screws threads were engaged for all tests: fully threaded, cortical screws, 3.5 mm in outer diameter, made of stainless steel (DePuy Synthes, Zuchwil, Switzerland). The material properties of the bone (TYS and f) were considered to be the same for all tests as the tibia tested was from one individual. Finally, as the cortical thickness was directly measured for each hole, only the tensile yield stress (*TYS*) and friction coefficient (*f*) remained as unknown variables. To calculate these, 20 holes, from four samples evenly distributed from along the length of the tibia (samples 1, 5, 10 and 15 of 15) were used for destructive testing to establish the relationship between cortical thickness (independent variable) and T_{str} (dependent variable); the rest of the samples were used for submaximal tightness testing. T_{str} was defined as the maximum torsional force that could be generated when rotating a screw. Screws were initially inserted by hand, through a compression load washer, mounted on bearings. Screw lengths were chosen to ensure at least 2 mm of screw threads had passed through to the inner aspect of the cortex. Each bone sample was only attached to the testing set up by the screw threads with a block added to prevent rotation of the bone specimen (Figure 5-1a). The base plate for the jigs used an X-Y plate to allow perpendicular screw insertion.

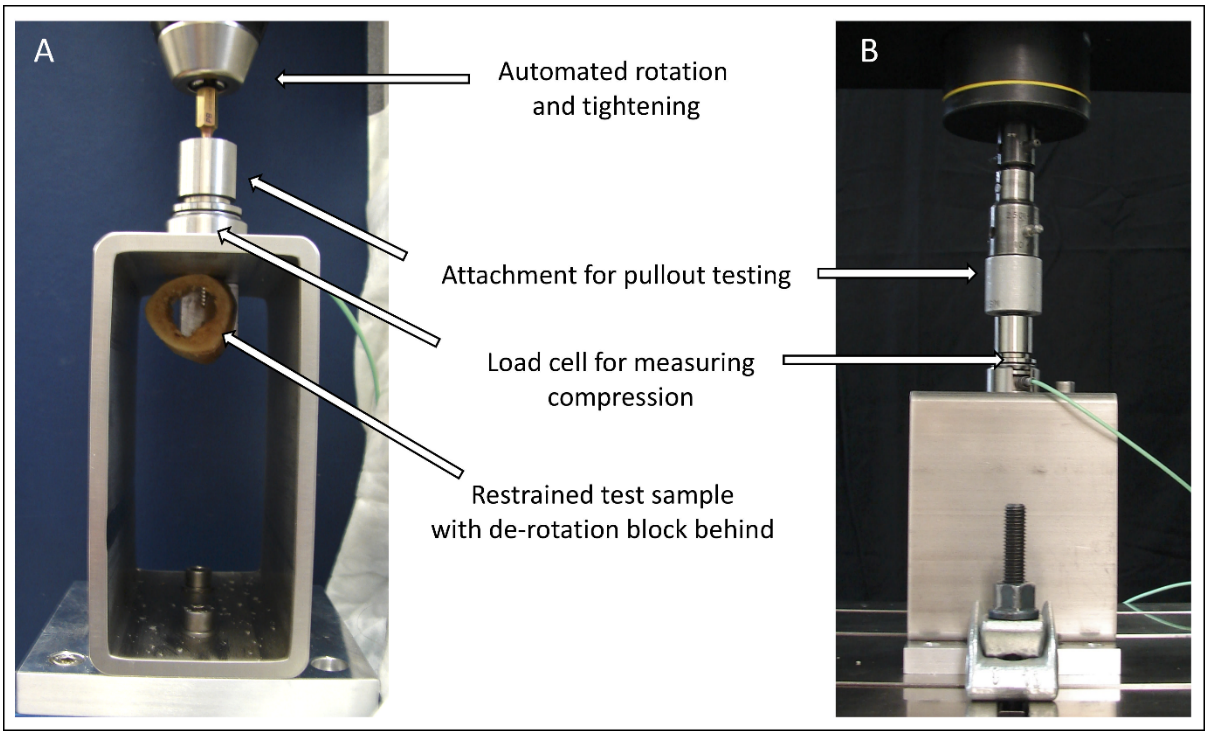

Figure 5-1 - Testing apparatus for automated insertion of screws with continuous compression recording (A) and material testing machine set up for pullout testing (B).

Using custom made software (Matlab v2018b, The MathWorks Inc., Natick, MA, USA), compression generated between the screw head and bone was recorded at 100 Hz. Constructs were mounted onto a material testing machine Instron 5943 (Instron, Norwood, MA, USA), that performed rotation of the screw at a constant rate of 7.5 revolutions per minute until stripping of the bone occurred (Figure 5-1a). Additionally, the torque averaged over the 60 degrees of rotation prior to screw head contact against the jig was chosen as representative, and was recorded as, the T_{plat}. For these stripped samples, when the post stripping compression force had reached a plateau, the testing jig was removed and transferred to a second material testing machine Instron 5866 (Instron, Norwood, MA, USA) for axial tensile testing (Figure 5-1b). The jigs used were designed to not disturb the fixation construct as the superior attachment on the compression jig could be screwed into the load cell for axial pullout. The jig was attached to the actuator of the testing machine, and axially loaded at 5 mm/min (ASTM, 2017), recording at 100 Hz until maximum force was observed. All force results were normalised according to cortical thickness.

Based on Equation 5-1, non-linear, least-squares data fitting (Matlab v2018b, The MathWorks Inc., Natick, MA, USA) was used to find the optimal values for the coefficient of friction and the tensile yield stress; initial conditions were set to 0.4(Parekh et al., 2013, Zdero et al., 2017b), and 90 MPa (Cowin, 1989, Parekh et al., 2013, Zdero et al., 2017b, Bayraktar and Keaveny, 2004), respectively. Regions of the solution search were bound between 0 and 1 for *f* and between 1 and 120 MPa for *TYS.* To validate these variables and Equation 5-1, half of the experimental stripping values were used to recalculate the *f* and *TYS*. This version of Equation 5-1 was then used to predict the stripping torques for the other 10 samples.

Investigating optimum tightness

Using the validated Equation 5-1, six values of targeted tightness were selected; 45, 55, 65, 75, 85 and 95% of the stripping torque. Using the cortical thickness for each hole, theoretical stripping torques were calculated and samples were randomised to a target tightness, with 11 samples per targeted value (total n=66). Based on the pilot testing, 11 samples would be needed per decile group to detect a difference of 100 ± 75 N/mm between groups at 80% power with an alpha of 0.05. Screws were inserted and tested as described above.

Statistical analysis was performed using a linear regression model to test for an overall effect of cortical thickness on experimental stripping torque, of experimental stripping torque on predicted stripping torque, of plateau torque on experimental stripping torque, of screw tightness on pullout force and compression force, and of cortical thickness on unnormalised pullout force. The adjusted R^2 values and the p-values were used to indicate how well the model fit the data. Normality of the data was analysed using Shapiro-Wilk tests. For compression forces, we analysed the impact of increasing screw tightness in more detail: we grouped tightness in 10%-blocks, centred around the targeted tightness integer i.e. 75% for 70-79%, and ran pairwise comparisons between every two of the tightness groups using a two-sided, independent samples t-test with unequal variances. Results for all statistical analysis were considered significant at an alpha of 0.05, with Bonferroni corrections used for multiple comparisons. Statistical analysis was performed using IBM SPSS Statistics for Windows, version 20 (IBM SPSS Corp., Armonk, N.Y., USA). Data is available via an online data repository(Fletcher et al., 2020f).

Results

Cortical thickness demonstrated a linear relationship with experimental stripping torque; $R^2 = 0.862$, $p<0.001$ (Figure 5-2a). Compression reduced by approximately 95% when screw holes were stripped compared to unstripped insertions (post stripping normalised compression 11 ± 7 N/mm (n=20) compared to maximum normalised compression 222 ± 69 N/mm (n=20)). The pullout force for stripped screw holes was reduced by 93% (32 ± 26 N/mm (n=20) compared to 468 ± 115 N/mm normalised pullout force, respectively (n=66)). To calibrate Equation 5-1, non-linear optimisation based on half of the initial samples (n=10) found a coefficient of friction of 0.269 and a tensile yield stress of 60.90 MPa. Using this version of Equation 5-1 to predict the T_{str} for the other 10 samples that were destructively tested, showed a significant and meaningful correlation between predicted and experimental T_{str} of $R^2=0.894$, $P<0.001$ (Figure 5-2b).

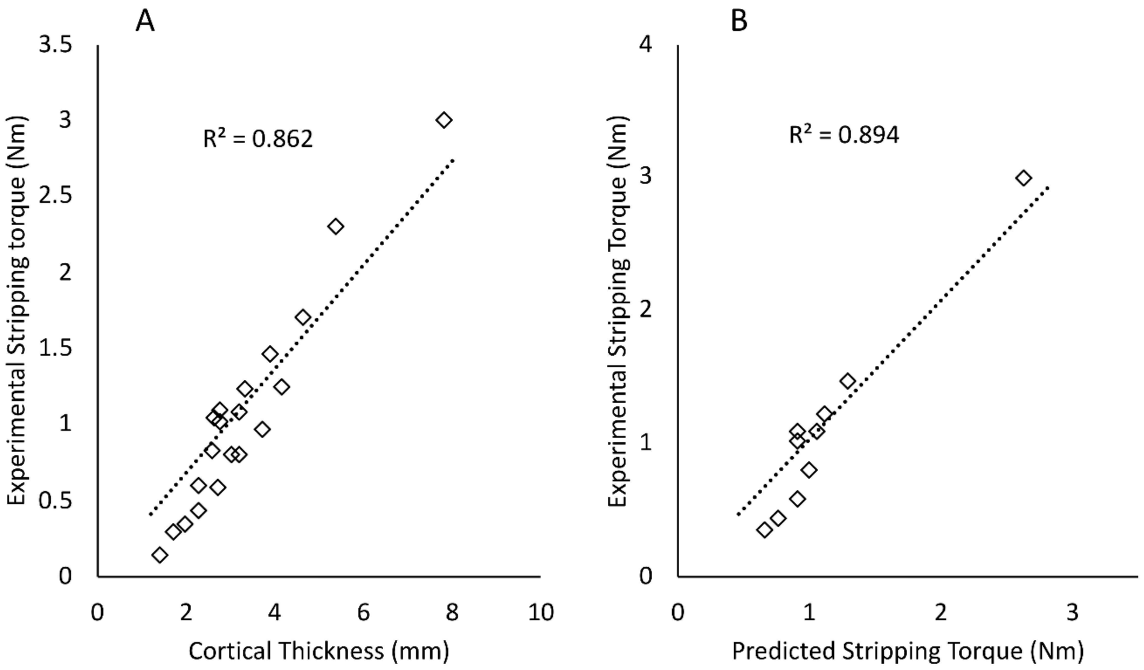

Figure 5-2 - Relationship between cortical thickness and experimental stripping torque for 20 samples (A) and relationship between the predicted stripping torque calculated using Equation 2 and the experimental stripping torque for 10 samples (B).

Plateau torque (T_{plat}) showed a relationship to experimental T_{str} of $R^2=0.901$, $P<0.001$, (Figure 5-3) described by the following equation:

Equation 5-2

$$T_{str} = 1.851 \cdot T_{plat} + 0.290$$

When investigating optimum tightness, 4/66 samples (7%) were inadvertently stripped and were excluded; statistical analysis was performed for the remaining 62 samples. When analysing all unstripped data points, as tightness increased, compression increased (R^2=0.495, P<0.001). However, when tightness groupings were compared for changes in the relationship between tightness and compression, further increases in tightness from 75% to 85% and 75% to 95% did not generate any significant increases in compression (both p=1.0) (Figure 5-4). Normalised pullout forces did not show any change as tightness increased between 40 and 100% of T_{str} (R^2 = 0.014, P=0.175), though pullout forces at 95% tightness were non-significantly less (P=0.060-0.655) than at all other tightness percentages (Figure 5-5). Finally, cortical thickness was found to correlate with unnormalised pullout forces (R^2 = 0.711, P<0.001).

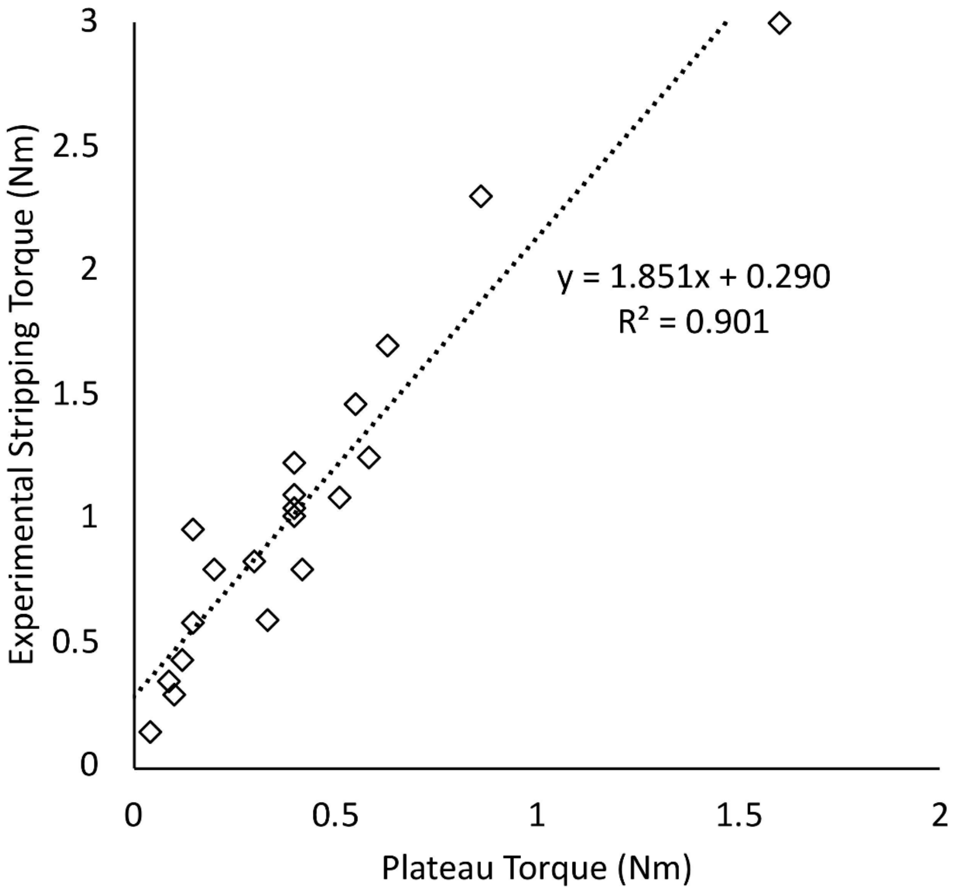

Figure 5-3 - Relationship between the plateau torque prior to screw head engagement and experimental stripping torque (n=20).

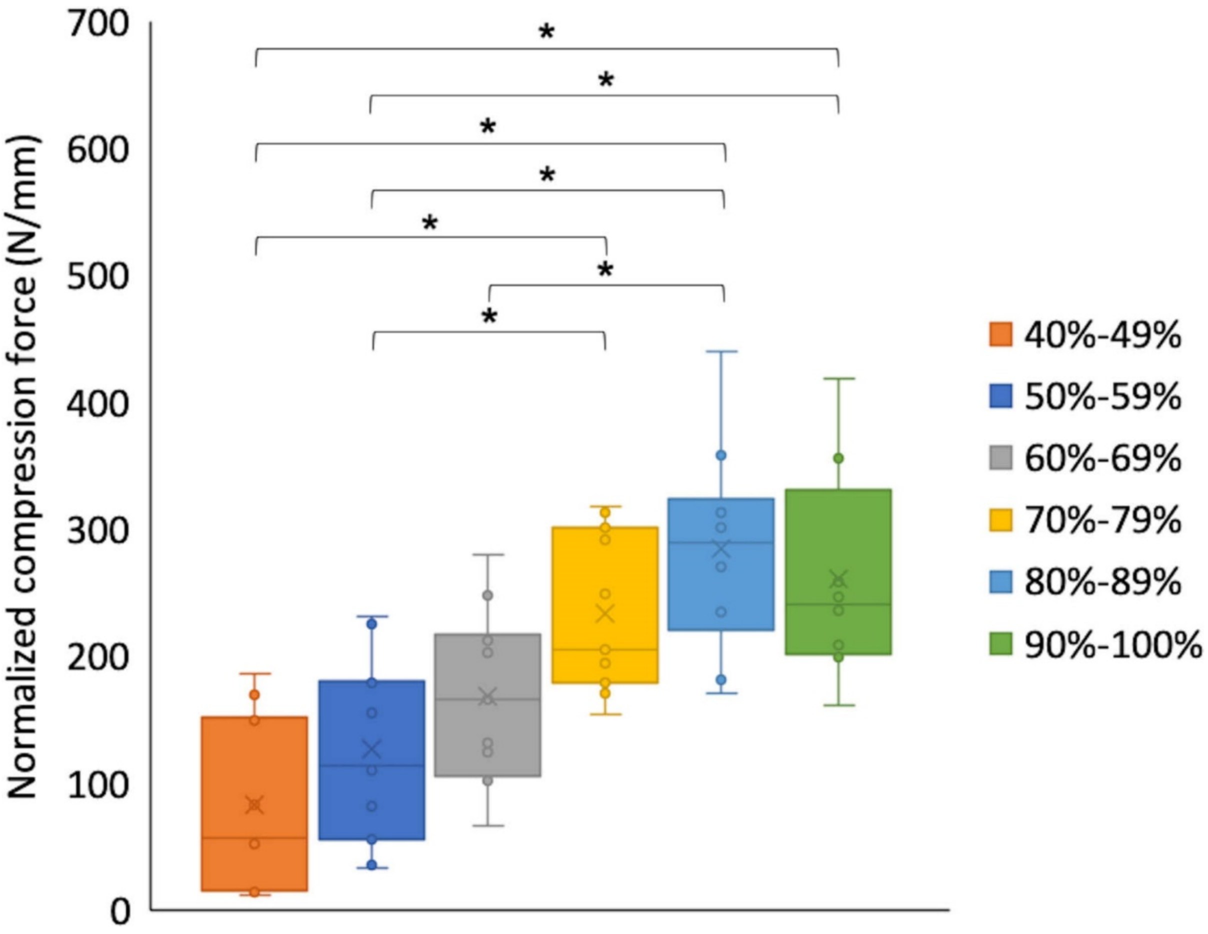

Figure 5-4 - Experimental values and box plot diagram of normalised compression force (N/mm) in decile groupings as functions of screw tightness (as a percentage of the stripping torque) (n=62).

*** indicates non-statistically significant comparisons; P>0.05.**

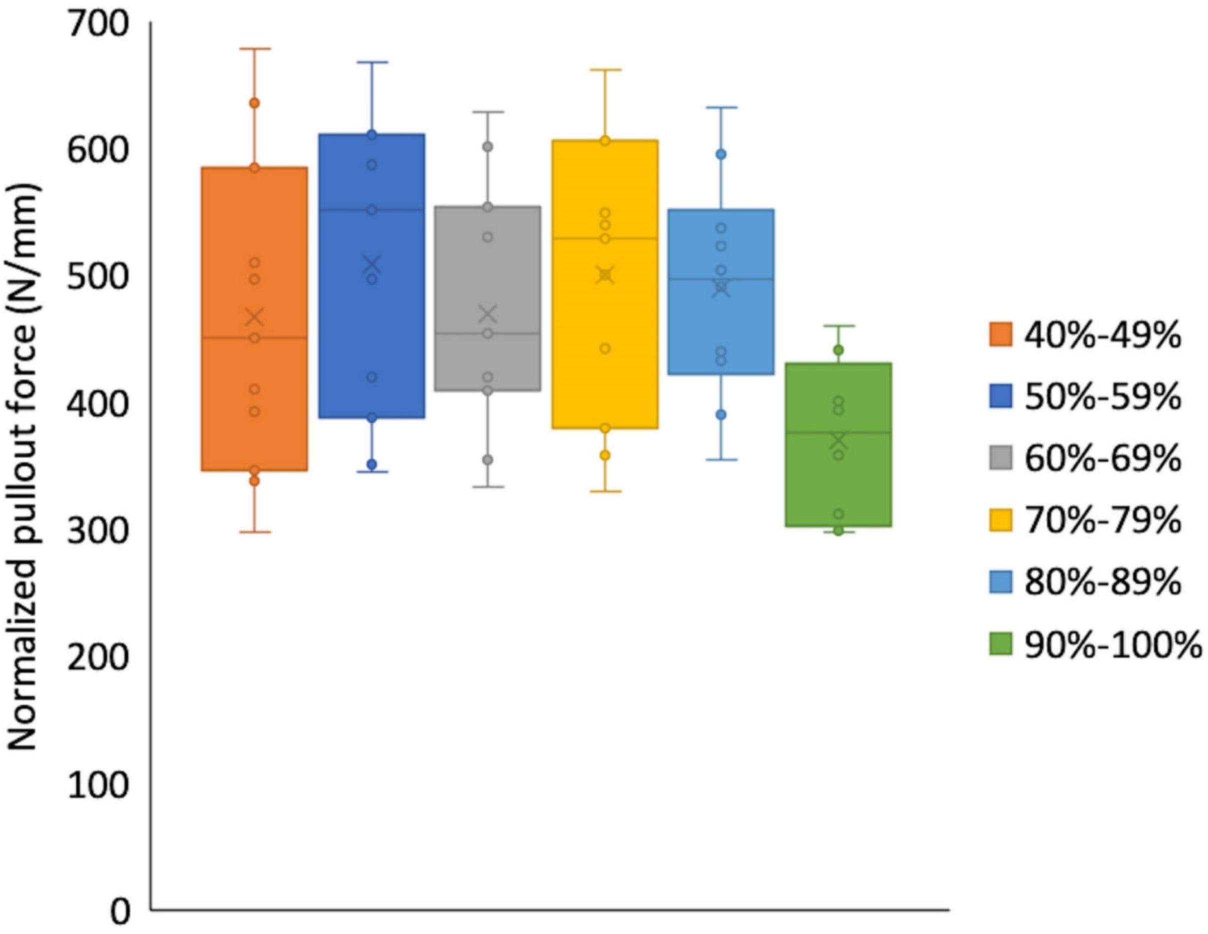

Figure 5-5 - Experimental values and box plot diagram of normalised pullout force (N/mm) in decile groupings as functions of screw tightness (as a percentage of the stripping torque) (n=62). There were no statistically significant comparisons; P<0.05.

Discussion

Maximum and optimum torques can be reliably calculated for cortical bone screw holes in human bone, with the latter being found between 70% to 80% of the stripping torque. The hypothesis that submaximal torques prove optimal can be accepted.

With 1 in 4 non-locking screws stripping the surrounding material when manually inserted (Fletcher et al., 2020d), any methods for identifying torque limits should help address these failures of surgical technique. The primary goal with screw insertion should be preventing stripping of the surrounding material, given that the compression and pullout forces reduce so dramatically if this occurs. Secondary objectives should include optimisation of the screw-bone construct by achieving the greatest compression, and the greatest pullout resistance. Using calculations based on bone material properties should increase the chances of achieving the primary goal as the proprioceptively unpredictable stripping limit can be foreseen, preventing the irreversible damage and complications that occur if exceeded.

The findings from this study can be implemented into clinical practice in several ways. Firstly, they show that more tightness, beyond 80% of T_{str}, does not produce any additional benefits to the construct. This means that tightening to the maximum torque is inadvisable. Secondly, using estimates of the tensile yield stress, even if these are only based on the cortical thickness and literature values for the friction coefficient and tensile yield stress, a targetable torque can be calculated preoperatively. This can reduce the chance of accidental stripping, which occurs all too commonly, especially in low density bone and during training (Fletcher et al., 2020d). As low energy fractures are likely to be associated with lower T_{str} due to lower tensile yield stresses of the bone, lower coefficients of friction and thinner cortices, using torque indicating screwdrivers that specify when predetermined torques are reached could reduce the chances of screws stripping the surrounding bone. This would be especially useful in situations where the stripping tightness in found well within the range of torques applicable by a surgeon; up to 2.0 Nm for 3.5 mm cortical screws (Jorge-Mora et al., 2019).

This study is the first to quantify optimum tightness in human bone, and supports previous work using a bovine model that also demonstrated how exceeding 80% of T_{str} gave no benefit to constructs regarding compression and pullout force (Fletcher et al., 2019). Other studies in juvenile ovine bone, showed tightening to 50% or 70% of the T_{str} (determined based on stripping a screw in the contralateral tibia) showed no difference in pullout force, but there was a significant ($P<0.05$) reduction from 70% to 90% of T_{str} (Cleek et al., 2007). However, compression was removed prior to pullout and the results were limited by having only 20 samples distributed amongst the three tightness groups.

Study limitations

In biomechanical testing, especially when using human bone, controlling all variables can be difficult. By using automated screw insertion to a target tightness, variability due to manual insertion was removed. However, in vivo, manual tightening may generate different findings. During screw insertion in this study, even using controlled automated insertion, four samples (7%) stripped the bone, meaning that overestimation of the stripping torque must have occurred in these cases; one when targeting 85% and three when targeting 95%. This is most likely to have arisen due to errors in measuring the cortical thickness and/or due to the heterogeneity of the cortical bone. This highlights that even under controlled laboratory conditions overtightening still occurred when targeting high percentages of the T_{str} - so may occur even more easily in less controlled operative environments. Given that no benefits could be seen in tightening beyond 80%, and that errors might occur in achieving 80% of the theoretical T_{str} in vivo, (due to inaccuracies in measuring bone properties), the case is strengthened for remaining in a safe torque range (between 70 and 80% of the maximum), away from the stripping limit.

The bone used was assumed as a homogeneous material to enable the predictions to be made. Whilst using the specimen of just one donor will have reduced the variability in bone characteristics, the *TYS* and coefficient of friction are likely to have varied between screw holes. Furthermore, as no direct measurement of the bone density was performed, these findings may not represent all bone types surgically encountered. It may be that the tightness beyond which there is no further benefit increases with denser bone – further studies using different densities are needed to establish this. Other materials such as titanium behave differently to stainless steel screws in fracture fixation (Hung et al., 2018) – the optimum tightness in other metals may be different to those in this study. Several variables within the study were at risk of error, such as the cortical thickness measured, and the perpendicularity of the screw holes. Though, as one researcher performed all sample preparations and screw insertions, inter-operator errors will have been eliminated. Whilst several other variables were controlled by using the same screw geometries each time, further work will be needed to validate these methods using different screw shapes and sizes, and in different regions of human bones. All screws were inserted only unicortically to ensure perpendicular orientation to the cortex, thus the findings may require validation in bicortical samples. However, it has been shown that splitting cortical thickness into a near and far cortex, rather than a single cortex of the same total thickness, does not seem to affect the relationship between cortical thickness and applied forces (Lawson and Brems, 2001, Kincaid et al., 2007, Ansell and Scales, 1968). Finally, the pullout testing methods used are only an assessment of the immediately implantation consequences and offer no assessment of healing effects, or of changes in constructs as stress dissipates over time and under loading. Future work will be required to implement methods for optimising fixation torques and measuring the clinical impacts from this.

Predictions of the stripping torque based on screw geometries and bone characteristics enable pre-insertion calculation of the optimum torque, found to be between 70% and 80% of the maximum. Further tightening once the screw head has made contact does not generate greater pullout forces, however increases the chance of stripping the surrounding bone – associated with reductions in compression and pullout force of more than 90%. Following further investigation using different screw geometries and considering the effect of bone healing, these findings can be incorporated into screw fixation strategies to ensure optimum torque is achieved intraoperatively.

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5.4 Summary

The findings in human bone were very similar findings to those in bovine bone, (Chapter 4), with compression increasing up to 80% of the stripping torque, with no benefit in going tighter than this, and an ever-increasing risk of stripping the screw hole. Equally, there was no significant change in pullout force with increasing tightness, though this was reducing above 90%.

These two chapters reinforce that there is an in vitro optimum tightness for screw insertion, and provide a robust method of calculating this prior to screw insertion. There were some inaccuracies with the calculations, shown with the stripping of some screw holes on insertion when targeting the higher torque percentages, likely due to errors in measuring the cortical thickness. However, these errors actually re-enforce the ideas behind this thesis - that even in controlled conditions, permanent damage to the bone can occur when attempting to tighten close to the maximum torque and new ways are needed to help surgeons insert screws for accurately and safely.

These experiments also highlighted the skill and dexterity needed when inserting screws, and how many different variables might impact on the outcome. When controlling my experiments, aspects such as the use of gloves or the type of screwdriver meant the feedback I had changed and may have led to different torques being applied. I felt these and other factors needed exploring, so the next research areas were to assess what else impacts on how screws are inserted, especially as any confounders to screw insertion might make enacting the findings of Chapters 4 and 5 harder and/or more variable. Alongside this, I felt that testing surgeons/researchers whilst using an augmented screwdrivers (modified to indicate when the optimum tightness was reached) would be a strong way to assess a way of practically applying the discovery of the optimum tightness. Screwdriver augmentation would seem to be a very safe way to improve screw insertion or at least be a way to help a surgeon develop their dexterity and proprioception, but this concept had only been looked at in a few previous studies and needed more evaluation.

Chapter 6 – Investigating the impact of different conditions on screw tightness and stripping rates

6.1 Context

When inserting screws, there are three categories of variables that can change when inserting screws and may alter the tightness:

- surgeon factors (awareness of torque, which hand, gloves),
- screw hole factors (density, thickness, type of bone (artificial or human))
- insertion factors (type of screwdriver, orientation of insertion and real-time awareness of applied torque).

It was not clear how these factors impact on the screw insertion performance, i.e. the tightness achieved and the rate of screw hole stripping. Screw insertion is a manual process that requires proprioception, dexterity and an ability to react appropriately to changes in the torque feedback. Based on my own surgical experience of screw insertion, I had witnessed that even when using the dominant hand, surgeons often showed poor screw insertion. However, sometimes the other hand might be used due to the access available, or different screws compared to normal are needed. This made me wonder how such factors and others might act as confounders to a surgeon’s performance. Additionally, screw insertion, given how commonplace, is an early skill a surgeon is exposed to. From a surgeon’s first operation, they may have the opportunity to insert screws. Whether there is a learning effect when inserting screws, especially with more uncommon sizes and/or uncommon techniques (such as using the non-dominant hand) had not been investigated but might highlight these areas as times when extra care is needed to ensure good screw insertion performance.

A final key aspect of screw insertion that needed considering was the need to standardise biomechanical testing so that any potential confounders are controlled for. Firstly, identifying potential confounders would enable future researchers to control for these but it may also prove to be another way of addressing the underpowered nature of other studies – if all of the common, potential are controlled for, then type 2 errors could be reduced.

6.2 Statement of Authorship

This declaration concerns the article entitled:			
Variations in non-locking screw insertion conditions generate unpredictable changes to achieved fixation tightness and stripping rates.			
Publication status (tick one)			
Draft manuscript ☐ **Submitted** ☐ **In review** ☐ **Accepted** ☐ **Published** ☑			
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Copyright status (tick the appropriate statement)			
I hold the copyright for this material ☐	Copyright is retained by the publisher, but I have been given permission to replicate the material here ☑		
Candidate's contribution to the paper (provide details, and also indicate as a percentage)	The candidate contributed to / considerably contributed to / predominantly executed the… Formulation of ideas: 90% Design of methodology: 80% Experimental work: 70% Presentation of data in journal format: 90%		
Statement from Candidate	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature.		
Signed		**Date**	07/08/2021

6.3 Study 5 - Variations in non-locking screw insertion conditions generate unpredictable changes to achieved fixation tightness

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Abstract

Screws are the most commonly inserted orthopaedic implants. However, several variables related to screw insertion and tightening have not been evaluated. This study aimed firstly to assess the effect of insertion variables on screw tightness, secondly to improve methodologies used by researchers when testing screw insertion techniques and thirdly to assess for any learning or fatigue effects when inserting screws.

Two surgeons tightened a total of 2,280 non-locking, 3.5 mm cortical screws, with 120 screws inserted to what they felt to be optimum tightness for each of the following conditions: different screwdrivers for measuring torque, screwdriver orientation, gloves usage, dominant/non-dominant hand usage, awareness to the applied torque (blinded, unblinded and re-blinded), four bone densities and seven cortical thicknesses. Screws were tightened to failure to determine stripping torque, which was used to calculate screw tightness – ratio between stopping and stripping torque.

Variations in bone density, the use of sterile gloves, torque unblinding and sample thickness >6 mm, all led to changes in the subjectively chosen optimum screw tightness. Considering all the insertions performed, the two surgeons stopped tightening screws at difference values of tightness (77% versus 66% ($p<0.001$)). A learning effect was observed with some parameters including sterile gloves usage and non-dominant hand application.

Different insertion conditions unpredictably changed screw tightness for both surgeons. Given the influence of screw tightness on fixation stability, the variables investigated within this study should be carefully reported and controlled when performing biomechanical testing alongside practicing screw insertion under different conditions during surgical training.

Keywords

Screw, tightness, stripping, non-locking, torque

Introduction

Screws are the most commonly used orthopaedic implants (Glauser et al., 2003). Biomechanical and clinical investigations into the techniques used for their insertion, and how successful these are, have shown that more than one in four non-locking screws have irreparably damaged (stripped) the surrounding bone on tightening (Fletcher et al., 2020d). Poor screw insertion can have considerable ramifications, as screw hole stripping leads to a reduction in pullout strength of more than 80% (Fletcher et al., 2020g, Fletcher et al., 2019, Wall et al., 2010), contributing to fixation failures (Broderick et al., 2013). Several basic variables related to screw insertion have not been evaluated with regards to changes in the tightness created by a surgeon or the incidence of screw hole stripping. For example, little is known on the impact of cortical thickness, glove usage or bone density on screw tightness.

This study firstly aimed to identify the effect of several factors on screw tightness and screw hole stripping rates, secondly to establish improved methodologies for testing surgical performance for future studies and thirdly, to assess for any learning or fatigue effect when inserting screws under different conditions.

Methods

Seven factors, which in total gave rise to 24 different possible values hereafter called parameters, related to screw insertion were selected for testing (Figure 6-1): 1) screw orientation (horizontal and vertical); 2) type of screwdriver (both torque measuring: 'Screwdriver 1' - DTS101 (Sushma Industries, Bangalore, India) and 'Screwdriver 2' - Premier STS103 (Jack Sealey LTD., Bury St. Edmunds, UK)); 3) dominant and non-dominant hand; 4) use of gloves (no gloves, unsterile gloves, single layer sterile and double layer sterile); 5) bone density (artificial bone (10, 20 and 40 pound-per-cubic foot (PCF) (Synbone, Zizers, Switzerland)) and human cadaveric tibiae); 6) cortical thickness (1, 2, 3, 4, 5, 6 and 7 mm); and 7) awareness of applied torque (surgeons blinded to the applied torque, then unblinded by seeing the torque value during insertion, before being reblinded). To investigate these factors, with the exception of the human cadaveric bone tests, a testing frame was developed to mimic the insertion of screws in a clinical situation: a high-density foam base was used onto which the artificial bone sheets were placed. Beneath the high-density foam, a second foam of lower density was used to simulate the reaction of surrounding human tissue during surgical treatment (Figure 6-2). In the artificial bone sheets, a total of 2160 pilot holes of 2.5 mm were made using a milling machine (FP1, Deckel Maho GmbH, Pfronten, Germany), based on a custom-made template using the screw configuration of 10-

hole, 3.5 mm locking compression plate (LCP, DePuy Synthes, Zuchwil, Switzerland). For the human bone tests, a single human cadaveric tibia (female, age 78) was used under local ethical approval. A total of 120 2.5 mm pilot holes were made in the diaphysis of this bone, using an automated bench drill (PDB 40, Bosch GmbH, Gerlingen, Germany). For all tests, stainless steel, fully threaded, cortical screws, outer diameter 3.5 mm (DePuy Synthes, Zuchwil, Switzerland) were pre-inserted until the screw heads were 3 to 5 mm distance from contacting a 3.5 mm, 10-hole limited bone contact dynamic compression plate (LC-DCP).

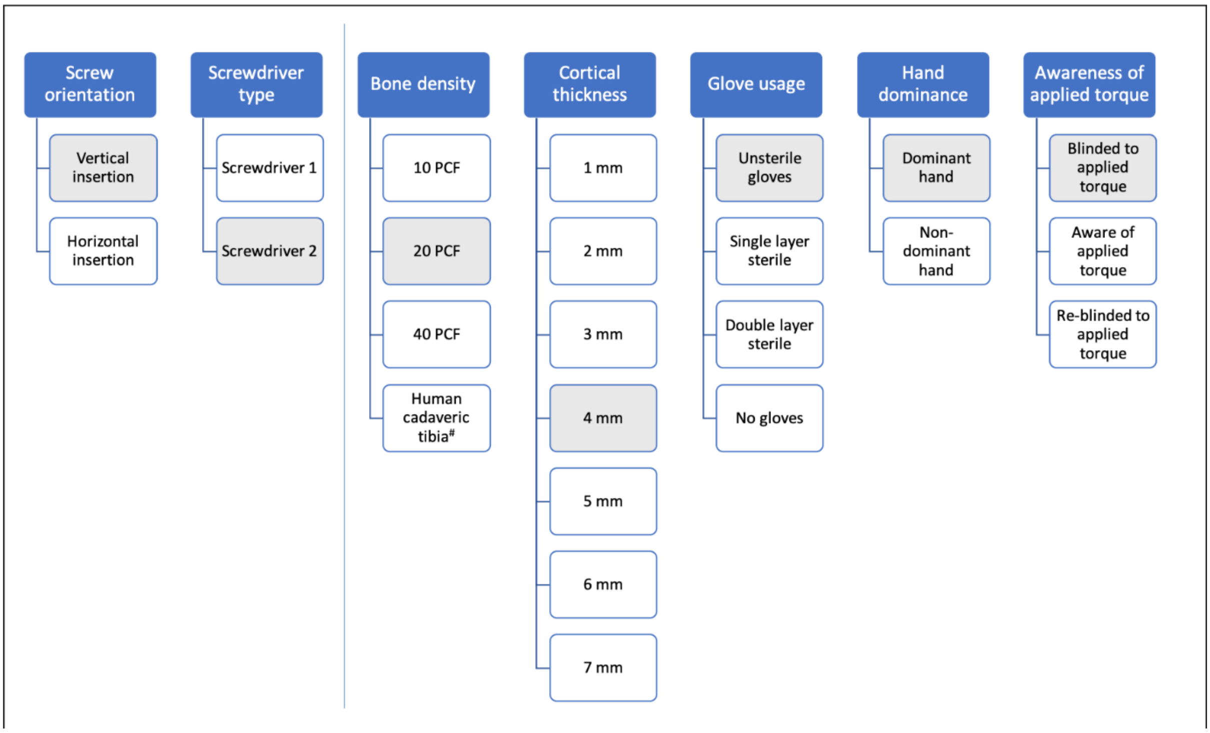

Figure 6-1 - Flow diagram of the parameters tested. Baseline parameters indicated with grey boxes – i.e. 4 mm thickness samples used when testing all glove variables. The dividing line indicates that the remaining five sub-studies were performed once the screwdriver and screw orientation tests had been analysed. N=60 screws tested per surgeon per variable.

Figure 6-2 - Testing apparatus – screw drill holes made following 10-hole, 3.5 mm LC-DCP template, with artificial bone sheet placed into dense foam, on top of a less dense foam – the latter mimicking the stiffness of human tissue.

Two orthopaedic residents were asked to tighten a total of 2,280 screws - 60 screws per surgeon per parameter, to what they felt was optimum tightness. Screw orientation and type of torque measuring screwdriver were investigated initially so that both of these variables could remain unchanged when testing the other parameters. In total, seven sub-studies were performed comparing the parameters within each variable group to others in that group but using the same baseline combination of factors (Figure 6-1). The baseline considered only a single parameter being changed at a time as follows: using a surgeon's dominant hand, wearing unsterile gloves, being blinded to the value of torque applied, tightening to what the surgeon determined optimal for construct stability (stopping torque), into 4 mm thick, 20 PCF artificial bone sheets using Screwdriver 2 in the vertical orientation (Grey boxes in Figure 6-1). Where the testing set up was duplicated between parameters, i.e. testing 4 mm cortical thickness which had already been indirectly investigated when testing 20 PCF density, only one set of results was used for both situations as these parameters were in the middle of any tested ranges where applicable.

After insertion of each screw, the torque value displayed on the screwdriver was recorded (stopping torque), with the surgeon blinded to this (except when specifically testing their unblinded technique). With the except of the human cadaveric bone tests, once all 60 screws for a parameter had been tightened by a surgeon, a researcher applied the maximum torque to each screw and recorded this as the torque needed to strip the material surrounding the screw (stripping torque). Due to the curvature of the human bone surfaces not allowing consistently flat placement of the plate, the stripping torque was measured after each screw insertion, whilst maintaining surgeon blinding. Tightness was defined as the ratio between stopping and stripping torques. If the stopping torque was greater than the torque achieved when subsequently attempting to strip the material, the screw hole was defined as having been stripped during insertion; this enabled calculation of the stripping rate. Only unstripped insertions were used to calculate the average tightness for a parameter. From preliminary testing, 50 screws were calculated to be needed per test scenario for 90% power at 5% level of significance based assumptions for detection of a mean 5% (SD 10) difference in tightness, with 10 extra tests performed in case of experimental issues.

Following One-Sample Kolmogorov-Smirnov tests for normality of distribution, the difference between the screw tightness and stripping rates for each variable for the combined results of both surgeons were compared using Mann-Whitney U Test tests for variables with two parameters and Kruskal-Wallis test for variables with more than two parameters. For each test variable, to assess for differences in screw tightness due to any learning or fatigue effect, using the Mann-Whitney U test, the first and the last 10 screw insertions were separately compared against all 60 screw insertions and then compared against each other (first 10 screws versus last 10 screws).

Results were considered significant at a level of significance 0.05, with Bonferroni corrections in cases of multiple comparison and confidence intervals set at 95%. Statistical analysis was performed using IBM SPSS Statistics for Windows, version 20 (IBM SPSS Corp., Armonk, N.Y., USA). All data are available in an online repository (Fletcher et al., 2020c).

Results

All insertions were performed successfully and included in the overall analysis. There was no evidence against the null hypotheses of there being no differences in screw tightness based on the screwdriver used ($p=0.098$), the orientation of insertion ($p=0.221$) or which hand was used ($p=0.234$). Wearing any gloves increased the tightness by 5 to 14% compared to no gloves used ($p \leq 0.018$), with single layer and double layer sterile gloves decreasing tightness by 9 and 8% respectively compared to unsterile gloves ($p=0.012$ and $p=0.006$). When the surgeons were unblinded to the insertion torque, tightness decreased by 9% ($p<0.001$) with a reduction in the stripping rate of 9% ($p=0.002$). On being re-blinded to the applied torque, tightness increased by 8% ($p<0.001$), though the stripping rate remained low (2%) ($p=0.563$). Screws inserted into 20 PCF and 40 PCF artificial bone, being compared to 10 PCF, showed reductions in tightness of 15% and 11% (both $p<0.001$), with no difference between 20 and 40 PCF ($p=0.846$). Stripping rates were also lower in the 10 PCF and human cadaveric bone tests (1 and 3%) compared to the 20 and 40 PCF (10% and 7%, respectively). There were few differences in tightness due to cortical thickness, with the exception of 7 mm insertions, where screws were 4-10% less tight (all $p<0.050$) than in all other thicknesses except when compared to the 4 mm samples ($p=0.102$). Additionally, 6 mm insertions were 6% less tight than 5 mm (p<0.001) and 3 mm insertions were 6% less tight than 5 mm (p<0.001). For seven parameters, tightness increased as more screws were inserted, with no situations where subsequent groups of screws were less tight than previous (Figure 6-3). No screw holes were stripped when gloves were not used nor in the 1 mm samples. All stripping rates were below 10% except for when using Screwdriver 1 (30%) and when inserting screws horizontally (11%). Screw tightness for all unstripped insertions was 77%, 95% CI [74-79] for surgeon A (n=1,034), and 66%, 95% CI [64-69] for surgeon B (n=1,110) (p<0.001). The overall stripping rates were 9% and 3% for surgeons A and B respectively (Figure 6-4).

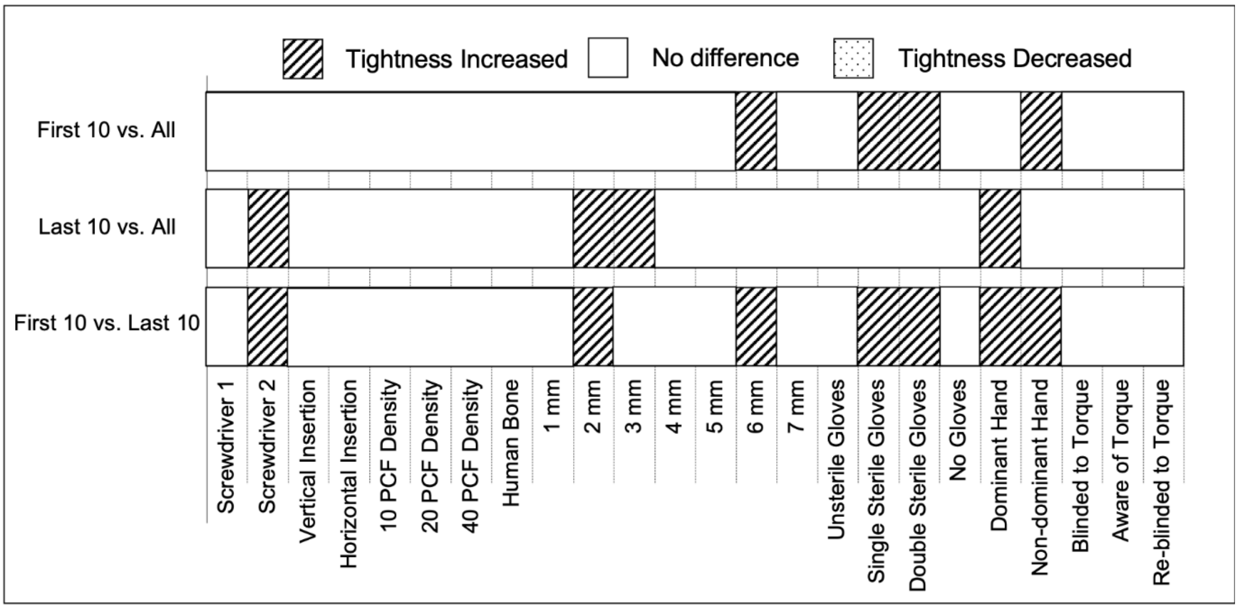

Figure 6-3- Differences (either learning effect (tightness increased) or fatigue (tightness decreased)) in combined tightness for both surgeons between first 10 and all screws, last 10 and all screws and first 10 and last 10 screws. Significant differences (p<0.05)

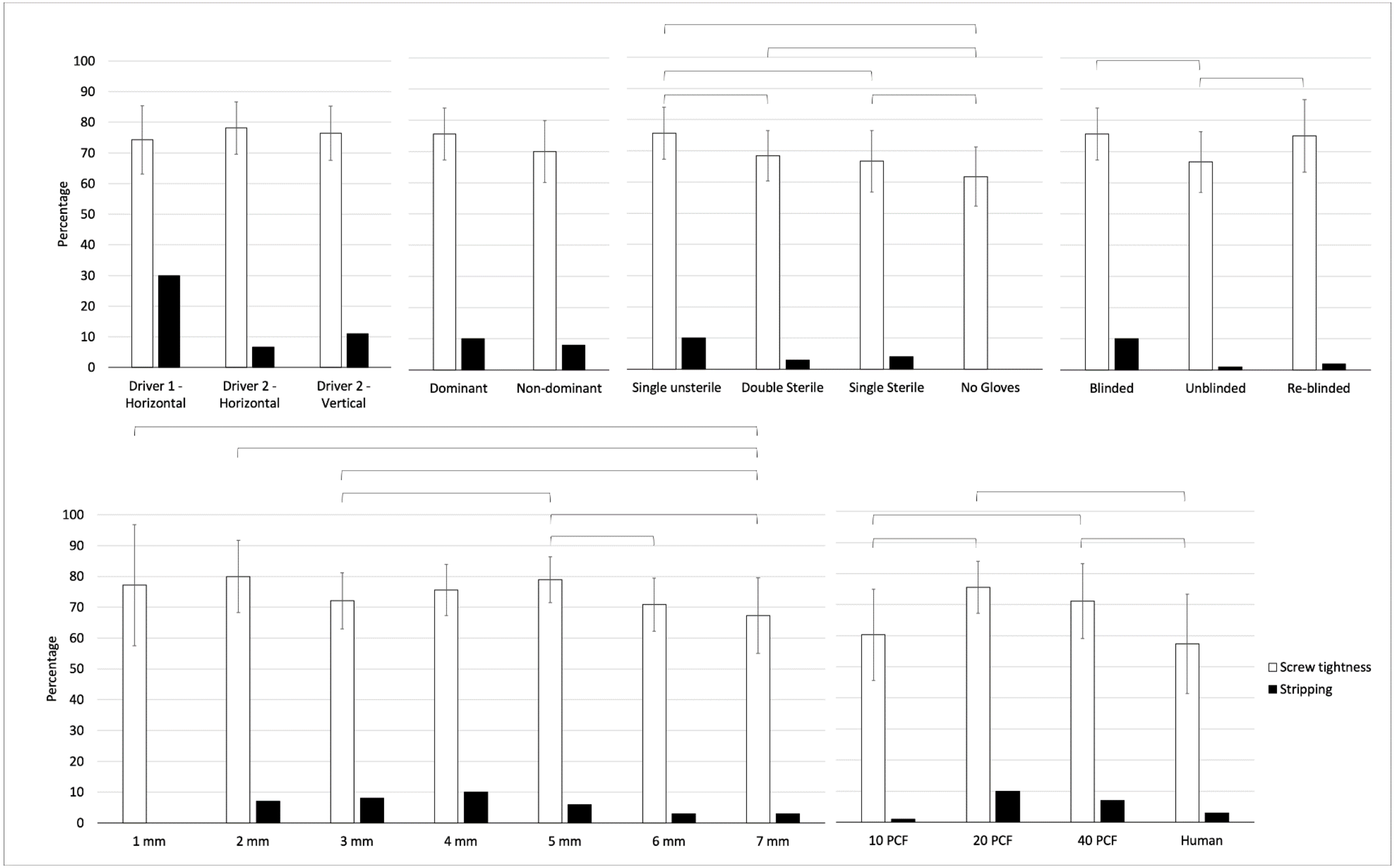

Figure 6-4 - Bar chart of the combined unstripped screw tightness and stripping rates for each variable for both surgeons; mean average indicated by columns and 95% confidence intervals indicated with error bars. Brackets indicate significant (p<0.05) between screw tightness

Discussion

Screw insertion is reliant on the decision making of the surgeon as to when the optimal tightness has been reached for a specific screw in its corresponding screw hole. We have shown that tightness and stripping rates are affected by insertion conditions, that feedback about the applied torque affects the quality of insertion and that many conditions show a learning effect. These findings have implications for research involving screw insertion and potentially impact on guidelines and clinical practice that such studies inform, as these variables should be controlled for and reported more accurately given the potential impact to screw fixation. Furthermore, in clinical practice and when training, awareness of the effects from different insertion parameters and screwdriver torque feedback are needed to optimise insertion techniques and minimise screw hole stripping.

The feedback from the resisting torque from the friction generated by screw thread compression at the bone-screw interface is likely to be the main determinant for how much further rotation of the screw is felt to be required. Prior knowledge of bone density, which influences the shear strength of the material, and cortical thickness, which determines the thread surface area engaged (Chapman et al., 1996), may narrow the expected range of torque values that will prove to be optimal for a screw. Furthermore, following the insertion of the first screw under the same testing conditions, the anticipated optimum torque may be recalibrated by a surgeon based on the proprioceptive feedback of how good the purchase is felt and/or whether the surrounding material was stripped during tightening. Cordey et al. (1980) suggested that the rate of increase in force against the rate of screw rotation is detected by surgeons and used to predict the optimum tightness (Cordey et al., 1980). However, it is questionable as to how detectable this is given the high incidence of stripped screw holes seen during biomechanical testing and in clinical practice (Fletcher et al., 2020d). Assuming that the rate of increasing force is felt and acted upon, either consciously or subconsciously, which torque value creates the best construct has previously been poorly defined, though recent in vitro work has shown it to be 70 to 80% of the maximum torque (Fletcher et al., 2020e). In addition to ensuring that screws are inserted below the maximum torque to prevent stripping (the primary objective), having an optimum tightness to target introduces a second aspect into the decision making required during screw insertion – making sure that the construct will be fixed at the best tightness (the secondary objective) (Fletcher et al., 2020e). Variables related to creating screw constructs were found to affect screw tightness and have impact on the quality of the fixation created. If a surgeon’s ability to moderate the torque applied is related to their proprioceptive sensitivity, changes to certain variables may make optimum tightness more difficult to achieve. Visual feedback affected the quality of screw insertion, seen when surgeons were unblinded to the applied torque. This shows the benefit of measuring the applied torque when inserting screws both in clinical situations and during biomechanical testing as knowing the torque changes how tight screws are inserted. Finally, we have shown that in many conditions, there is a learning effect due to multiple repetitions. Thus biomechanical studies with small numbers of screws are potentially not only at risk of being underpowered due to small sample sizes, but that the tightness applied to screws may considerably change as more screws are inserted, which given that insertion torque correlates with the applied compression (Fletcher et al., 2019, Fletcher et al., 2020g), may influence biomechanical testing data.

Two of the factors examined changed the stripping torque due to alterations in the quantity of bone available for purchase by the screw threads through changes in thickness or density (Troughton, 2008). Screw tightness was found to be lowest in the 10 PCF, where extra attention to the risk of stripping may have been employed, as the stripping torques were very low, and could have been anticipated to be easily exceeded; average stripping torque was 0.05 Nm. However, the stripping torque for the human bone used in this study (0.41 Nm) was between that of the 20 PCF (0.17 Nm) and the 40 PCF (0.55 Nm), yet the tightness in the human bone used in this study was significantly less than both, with a lower rate of stripping. Whilst the theory of extra attention being paid in situations where low stripping torques could be encountered is echoed in the cortical thickness findings, where neither surgeon stripped any screws in the 1 mm samples, this theory does not explain why human bone tests showed low stripping rates and may be more related to the different mechanical characteristics of human bone testing and the variable cortical thickness of the screw holes in human bone.

The increased challenge to optimally insert screws under some conditions could be reflected by the differences between the tightness of the first 20 screws, all screws and the last 20 screws per variable. As more screws were inserted, the average tightness increased for seven parameters (p<0.001-0.049), with no decrease in screw tightness seen as more screws were inserted under any of the tested conditions. This may show a learning effect, as increasing knowledge of a screw insertion situation is acted upon, with growing confidence to apply more torque. The learning effect could explain the increased tightness seen with non-dominant hand, double and single sterile gloves, as these were all conditions where there had been a change to the proprioception, either by using a less familiar hand or the thickness and feeling from surgical gloves.

Tsuji et al. (2013) investigated screw tightness in artificial and human bone using cortical and cancellous screws inserted by a single surgeon (Tsuji et al., 2013). They found that in artificial bone, cortical screw tightness decreased (R = -0.63) as density increased from 5 to 50 PCF. The findings from our study contradict this, as there was a significant increase in tightness between the least and most dense samples, however a tighter range of artificial bone densities was used in this study (10 to 40 PCF). Also investigating the effect of density, Stoesz et al. did not find any difference in tightness (p=0.299) or stripping rate (p=0.186) when 10 surgeons inserted 10 cancellous screws into artificial bone blocks of 5, 10 and 20 PCF (Stoesz et al., 2014). Having three contradicting findings for the same factor may reflect the how different surgeons respond to different factors, and/or the underpowered nature of the other studies due to a small number of screw insertions per variable.

Blinding to applied torque

With unblinding of the applied torque during screw insertion, stripping rates reduced considerably. Even without a pre-insertion torque value to target for the optimal tightness, being able to quantitatively know the applied torque seems to have helped the surgeons when tightening screws. Gustafson et al. first used this method of blinding, unblinding and then re-blinding surgeons to the torque they had applied (Gustafson et al., 2016). They also found that stripping rates decreases when surgeons were aware of the quantitative torque being applied, though on re-blinding, the stripping rate they observed returned to the baseline level.

Dominance

Screw insertion either clinically or in biomechanical testing studies using a non-dominant hand is uncommon, however the variation in tightness highlights that extra care is needed if this occurs given the increase in tightness seen between the non-dominantly inserted first 20 screws, all 120 screws and last 20 screws (65%, 70% and 85% respectively).

One other study has compared tightness when surgeons used both their dominant and non-dominant hands (Acker et al., 2016). Acker et al. did not report tightness data for the non-dominant hand, just that there was a small tightness difference (9%) between each hand for the senior surgeons and that the only individuals with more than 70% difference were first- and second-year residents. However, senior surgeons stripped nearly twice as many screw holes with their dominant hands than first and second year residents, again highlighting that there are two key components to ensuring good screw insertion - firstly not stripping screw holes and secondly achieving optimum tightness - with variation in screw tightness being far less of a consequence than greater stripping rates (Fletcher et al., 2019).

Glove usage

In clinical practice, screws will be inserted with the surgeon wearing gloves, so it is surprising that no biomechanical studies into screw tightness have stated the use of them in their methods; the only paper that is assumed to have used them when investigating screw tightness involved during ankle fixation (Andreassen et al., 2004). This is especially important given that no gloves, sterile gloves (either single or double) and unsterile gloves all generated different tightness. In biomechanical testing, glove usage may be inconsistent depending on the contamination risk of the model being used, but it is likely to involve the use of unsterile gloves to reduce costs. Given the difference in tightness when only changing the gloves used for screw insertion, this may impact on the clinical transferability of findings that do not replicate clinical glove usage.

The total number of screw insertions performed within this study is 9.5 times larger than the next nearest studies to date into screw tightness under different conditions (Stoesz et al., 2014, Gustafson et al., 2016). With 120 screws inserted per condition, aspects such as learning and fatigue effects could be investigated - factors that may have been overlooked in smaller studies (Fletcher et al., 2020a). Whilst this study was strengthened by being appropriately powered and using more than one surgeon, the different variables affecting the surgeons' performances may highlight the subjectivity of screw insertion. Using more surgeons may have reduced the impact of this limitation and made the specific findings more transferable to other surgeons. However, the purpose of this study was to investigate the differences caused by variations in factors related to screw insertion and finding that all such variables can lead to unpredictable differences in tightness means that they should all be controlled in testing. A second limitation of this study is that bias may have been introduced by having participants who knew the aims of the project before inserting and knowing that the tightness of their screws would be measured may have changed their behaviour compared to uncritiqued insertions. However, the aim of the research was to compare the effect of different factors rather than detailed analysis of how and why each surgeon tightened their screws. Thirdly, no assessment was undertaken of how the fixation changes as the tightness varied, such as measuring the compression generated or the fixation strength, though previous work has shown that if screw holes are stripped, it reduces compression and pullout strength by more than 80% (Wall et al., 2010, Fletcher et al., 2019, Fletcher et al., 2020g). Fourthly, artificial bone was predominantly used given its highly homogeneous properties especially compared to human models, but the transferability of some of the findings may be limited as human bone may behave differently. Finally, the cortical thickness of the human bone screw holes varied and may have been a confounder to these tests.

Conclusion

Variations in conditions related to screw insertion led to significant changes in screw tightness and stripping rates. Given the differences seen, methodologies involving non-locking screws should report the conditions of screw insertion and standardise them throughout testing to control for these potentially confounding factors. Surgical training should incorporate technique assessments for surgeons so that they can safely understand the tightness applied to screws under different conditions.

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6.4 Summary

Several variables related to screw insertion impact on tightness and stripping rates. These findings justify increased control of such confounders in biomechanical testing as they raise questions about other studies where these variables were not reported or controlled - a lack of control of these may have unknowingly impacted on their findings. This study also showed the need for increased awareness of the potential impact in clinical practice of factors such as different glove usage. Ultimately, the findings highlighted that if there was an opportunity for surgeons to practice in different environments and calibrate themselves, it might improve their clinical performance as there are many potential factors that will change the feedback they get when inserting screws.

The improvement seen with screwdriver augmentation proved an interesting finding, which would be further explored in the next chapter. This might show a role for augmentation in surgical education, given how performance improved, which would be especially powerful in early years training given how these are skills that are needed throughout one's career.

Chapter 7 – Comparing the screw insertion outcomes of biomechanical researchers and orthopaedic surgeons

7.1 Context

Having established methods for controlling potential confounders when evaluating screw insertion, the final consideration regarding screw insertion was the potential differences between biomechanical researchers who are often making *in vitro* research discoveries, and surgeons who insert screw *in vivo* and attempt to translate laboratory findings into clinical practice. The research question in this chapter addressed whether there is a difference in the performance of biomechanical researchers and practicing surgeons. Differences between them could impact the clinical transferability of any laboratory-based research. Furthermore, if there were differences in performance between the groups, I questioned whether these differences could be negated by using a screwdriver that indicated to the user when the optimum tightness had been reached. This could mean that regardless of the background experience of the screw inserter, techniques could be optimised through augmentation.

7.2 Statement of Authorship

This declaration concerns the article entitled:	
Biomechanical researchers have lower stripping rates than orthopaedic surgeons when inserting non-locking screws	
Publication status (tick one) **Draft manuscript** ☐ **Submitted** ☐ **In review** ☐ **Accepted** ☐ **Published** ☑	
Publication details (reference)	Fletcher et al., Screw tightness and stripping rates vary between biomechanical researchers and practicing orthopaedic surgeons. Journal of Orthopaedic Surgery and Research. 2021:16, 642
Copyright status (tick the appropriate statement) I hold the copyright for this material ☑ Copyright is retained by the publisher, but I have been given permission to replicate the material here ☐	
Candidate's contribution to the paper (provide details, and also indicate as a percentage)	The candidate contributed to / considerably contributed to / predominantly executed the… Formulation of ideas: 90% Design of methodology: 80% Experimental work: 70% Presentation of data in journal format: 90%
Statement from Candidate	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature.
Signed	**Date** 07/12/2021

7.3 Study 6 - Screw tightness and stripping rates vary between biomechanical researchers and practicing orthopaedic surgeons

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Chapter 7 – Comparing the screw insertion outcomes of biomechanical researchers and orthopaedic surgeons

Abstract

Screws are the most frequently inserted orthopaedic implants. However, they are often inserted poorly, increasing the rates of fixation failure. Most biomechanical studies will use biomechanical trained, non-surgically practicing researchers, whose research findings are translated into clinical practice. However, limited data exist on the comparative performance of surgically and non-surgically trained biomechanical researchers when inserting screws. Furthermore, any variation in performance by surgeons and/or biomechanical researchers may be adding a currently underappreciated confounder to biomechanical research findings. This study aims to identify the association between surgically and non-surgically trained biomechanical researchers' achieved screw tightness and stripping rates with different fixation methods.

Ten orthopaedic surgeons and 10 researchers each inserted 60 cortical screws into artificial bone, for three different screw diameters (2.7, 3.5 and 4.5 mm), with 50% of screws inserted through plates and 50% through washers. Screw tightness and confidence in screw purchase were recorded. Three members of each group also inserted 30 screws using an augmented screwdriver.

Unstripped screw tightness for orthopaedic surgeons and researchers was 82% (n=928, 95% CI 81-83) and 76% (n=1,470, 95% CI 75-76) respectively ($p<0.001$); surgeons stripped 48% (872/1,800) of inserted screws and researchers 18% (330/1,800). Using washers was associated with increased tightness (80% (95% CI 80-81), n=1,196) compared to screws inserted through plates (76% (95% CI 75-77), n=1,204) ($p<0.001$). Researchers were more accurate in their overall assessment of screw insertion (86% vs 62%). No learning effect occurred when comparing screw tightness for the first 10 insertions against the last

10 insertions for any condition (p=0.058-0.821). Augmented screwdrivers, indicating optimum tightness, reduced stripping rates from 34% to 21% (p<0.001). Experience was not associated with improved performance in screw tightness or stripping rates for either group (P=0.385-0.965).

Surgeons and researchers showed different screw tightness under the same conditions, with greater rates of screw hole stripping by surgeons. This may have important implications for the reproducibility and transferability of research findings from different settings depending on who undertakes the experiments.

Keywords

Researcher, Screw, Stripping rate, Surgeon, Tightness, Torque

Introduction

Screws are the most commonly used orthopaedic implant and are needed in the majority of orthopaedic operations. In current practice, screws require the user's subjective assessment of the torque that should be applied to achieve optimum fixation. Analysis of surgical techniques has shown a concerning spectrum of abilities in creating adequate constructs for osteosynthesis (Fletcher et al., 2020d, Fletcher et al., 2020e). Screw insertion is potentially deemed a trivial procedure, for example, in orthopaedic surgical training there is no specific quantitative assessments of screw insertion abilities (Joint Committee on Surgical Training, 2017). Previous studies, with one exception (Fletcher et al., 2020a), into insertion techniques and their effects have usually been limited by involving only one surgeon inserting all screws (Aziz et al., 2014, Tsuji et al., 2013, Reitman et al., 2004, Feroz

Dinah et al., 2011, Mears et al., 2015), or several surgeons each inserting only a few screws (Fletcher et al., 2020e, Fletcher et al., 2019, Cordey et al., 1980, McGuire et al., 1995, Acker et al., 2016, Gustafson et al., 2016, Stoesz et al., 2014, Wilkofsky et al., 2014, Andreassen et al., 2004). There are no existing studies comparing and contrasting the outcomes of non-surgical, biomechanical researchers despite the numerous studies into screw fixation performed by them (Fletcher et al., 2020d). Furthermore, limited data exist on the screw tightness commonly achieved by surgeons and researchers and the effect on this from variations in parameters such as screw diameter (Fletcher et al., 2020d, Fletcher et al., 2020a). Given that biomechanical research is often performed by non-surgical researchers, differences in the abilities between surgical and non-surgical researchers could have considerable repercussions for the clinical transferability of findings generated by the latter.

This study was designed to assess a sample of orthopaedic surgeons and biomechanical researchers, with the null hypothesis of there being no difference in screw tightness and stripping rates under the defined conditions. The following comparisons were made to investigate the difference in screw tightness and screw hole stripping rates, firstly, between surgeons and researchers, secondly when inserting screws into plates or through washers, thirdly when inserting different diameter screws, fourthly, to ascertain any difference in reported confidence in screw insertions that had or had not stripped screw holes, fifthly any difference in detecting stripping of screw holes by surgeons and researchers, sixthly, the presence of a learning effect when inserting screws and finally whether awareness of applied torque and indication of optimum tightness affected screw tightness and stripping rates.

Materials and methods

Custom made testing apparatus was created for standardised screw insertion. Artificial bone sheets (Synbone, Zizers, Switzerland) were manufactured, 4 mm thick, with a density of 20 pounds per cubic foot (PCF). Using a milling machine (FP1, Deckel Maho GmbH, Pfonten, Germany), 90 drill holes were made perpendicularly in each of 40 sheets; each sheet contained 30 drill holes of 2.0 mm, 2.5 mm and 3.2 mm to receive 2.7 mm, 3.5 mm and 4.5 mm cortical screws respectively. A wooden jig was created, containing a foam base to mimic the stiffness of human soft tissue (Figure 7-1).

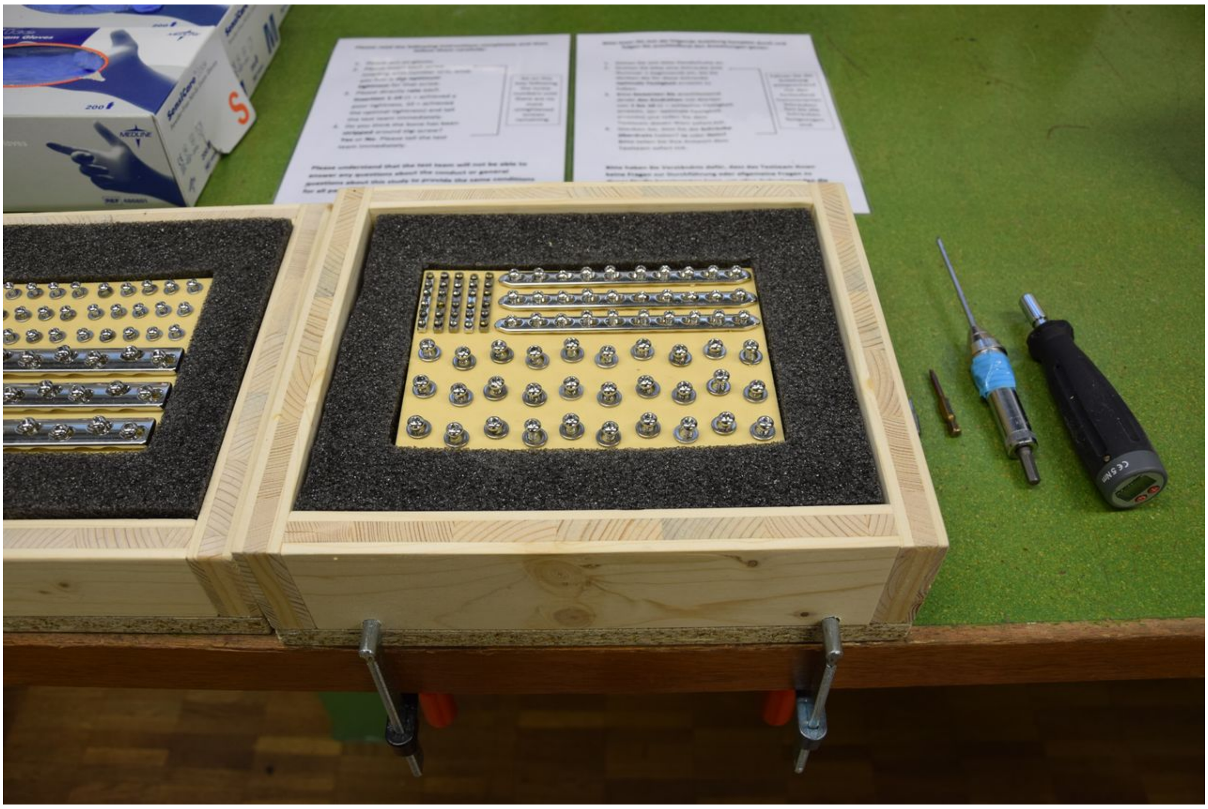

Figure 7-1 - Jig set up for insertion testing, with foam base mimicking human tissue stiffness.

Screw holes were made in the foam using the template so that screw threads would only engage in the artificial bone, whilst the remaining foam provided stiffness to the construct. Pilot testing had shown that 24 screws would be needed to detect a difference of

10±12% in tightness with 80% power at a significance of 0.05; this was increased to 30 screws in case of experimental issues. All screws (De Puy Synthes, Zuchwil, Switzerland) were stainless steel, self-tapping and fully threaded. Participants were asked to insert a total of 180 screws, with 60 inserted for each of the three screw diameters; 30 through washers and 30 through plate holes of the respective size for that screw. To ensure that toggle from initial insertion was not introduced by participants and that all screw insertions were started in a similar fashion, two study investigators pre-inserted all screws 3 to 5 mm from the surface of the plate or washer before being tightened by the participant.

Ten visiting surgeons and 10 biomechanical researchers were recruited from the AO Research Institute Davos, Davos, Switzerland; participants gave informed consent for assessment of their techniques. The number of years of experience in their respective fields was recorded. All tests occurred with only the test participant and investigators present, to remove any confounding due to peer distractions (Acker et al., 2016). Participants were blinded to the torque being applied. The ordering for the six testing conditions was randomised between participants using a simple sequence randomisation. Participants were given the same written instructions, including to wear unsterile, single layer nitrile gloves and to tighten each screw to what they determined to be the optimum tightness (Fletcher et al., 2020a). Each screw was tightened using a torque measuring screwdriver (Premier STS103, Jack Sealey LTD., Bury St. Edmunds, UK), with the screwdriver bit changed to match the screw drive. Each screw was used 12 times, with screws and screwdriver bits changed if any macroscopic damage occurred. Participants were asked after every screw insertion whether they felt the screw hole had been stripped, and to rate their confidence in the screw's holding ability from 1-10 (1 being very poor and 10 being optimal). After each screw was tightened, the stopping torque was recorded by a study investigator, with the participant blinded to the value. After all screws had been tightened by participants to the perceived optimum, investigators overtightened each screw to determine the stripping torque for that screw hole – defined as the maximum torque recordable for that screw in that screw hole. This was compared to the stopping torque to determine the screw tightness – as a ratio of stopping to stripping torque. If the stopping torque was greater than the stripping torque, it was recorded as having stripped the screw hole; this enabled calculation of the stripping rate.

Following initial analysis, the participants with the 1st, 5th and 10th highest stripping rates from both the surgeons and researchers were asked to re-attend on a different day to insert a further 60 3.5 mm screws through plates. With these insertions, half were performed as per their normal technique, followed by half with participants unblinded to the applied torque, with the screwdriver (Premier STS103, Jack Sealey LTD., Bury St. Edmunds, UK) set to vibrate and alarm when the optimum tightness was reached; optimum tightness was set at 70% of the average stripping torque (Fletcher et al., 2020a, Fletcher et al., 2020e, Fletcher et al., 2019), which was calculated by averaging the stripping torque for all previous insertions of 3.5 mm screws.

Statistical analysis was performed using unpaired, two-tailed t-tests for comparisons of years of experience, screw tightness and stripping rates for surgeons and researchers, and paired two-tailed t-tests for comparisons between tested variables: for plates and washers, for different screw diameters, for reported confidence for stripped and unstripped insertions, for the first ten screw insertions against the last ten screw insertions and for unaugmented and augmented screw insertions. Rates of screw hole stripping were compared using McNemar and Chi Squared tests. Bonferroni corrections were performed for cases of multiple comparisons, with adjusted values reported. Using the confidence values reported, the sensitivity, specificity and accuracy for screw hole stripping were calculated. Results were considered significant at a level of significance of 0.05, and confidence intervals were calculated at 95%. Statistical tests were performed with IBM SPSS Statistics for Windows, version 20 (IBM SPSS Corp., Armonk, N.Y., USA). All data is available in an online repository (Fletcher et al., 2020b).

Results

A total of 3,960 screw insertions were performed, with all available for analysis. Average experience was four years (range 1-19) for surgeons and 10 years (range 3-26) for researchers ($p=0.09$).

For all unstripped insertions, screw tightness was higher for surgeons (82% (95% CI 81-83), $n=928$) than for researchers (76% (95% CI 75-76), $n=1,470$) ($p<0.001$), with a greater stripping rate: 48% (872/1,800) vs. 18% (330/1,800) ($p<0.001$). Tightness and stripping rates for different screw diameters and plate and washer insertions are summarised in Table 7-1. Odds ratios for stripping under different conditions are shown in Figure 7-2. Higher screw tightness was seen for screws inserted through washers compared to plates ($p<0.001$). Lower tightness was seen with 4.5 mm insertions compared to 3.5 mm insertions for both surgeons ($p<0.001$) and researchers ($p=0.04$) and compared to 2.7 mm insertions for researchers ($p<0.001$). For surgeons and researchers, there was no association between experience and either screw tightness ($R^2=0.099$, $P=0.385$ and $R^2=0.021$, $P=0.687$) or stripping rates ($R^2=0.000$, $P=0.965$ and $R^2=0.058$, $P=0.502$) (Figure 7-3).

Table 7-1 - Tightness and stripping rates for researchers and surgeons under different testing conditions

		Number of insertions attempted	Number of unstripped insertions	Stripping rate (%)	Statistical difference in stripping rate	Unstripped screw tightness (%) (95% CI)	Statistical difference in tightness
All insertions	All participants	3,600	2,400	33		78 (78-79)	
	Surgeons	1,800	928	48	P<0.001	82 (81-83)	P<0.001
	Researchers	1,800	1,470	18		76 (75-76)	
Plate insertions	All participants	1,800	1,204	33		76 (75-77)	
	Surgeons	900	472	48	P<0.001	82 (80-83)	P<0.001
	Researchers	900	732	19		72 (71-74)	
Washer insertions	All participants	1,800	1,196	34		81 (80-81)	
	Surgeons	900	458	49	P<0.001	83 (82-84)	P<0.001
	Researchers	900	738	18		79 (78-80)	
2.7 mm insertions	All participants	1,200	670	44		79 (78-80)	
	Surgeons	600	218	64	P<0.001	83 (81-85)	P<0.001
	Researchers	600	452	25		77 (76-79)	
3.5 mm insertions	All participants	1,200	835	30		80 (79-81)	
	Surgeons	600	331	45	P<0.001	84 (83-85)	P<0.001
	Researchers	600	504	16		77 (76-78)	
4.5 mm insertions	All participants	1,200	885	26		77 (75-78)	
	Surgeons	600	381	37	P<0.001	80 (79-82)	P<0.001
	Researchers	600	504	16		74 (72-76)	

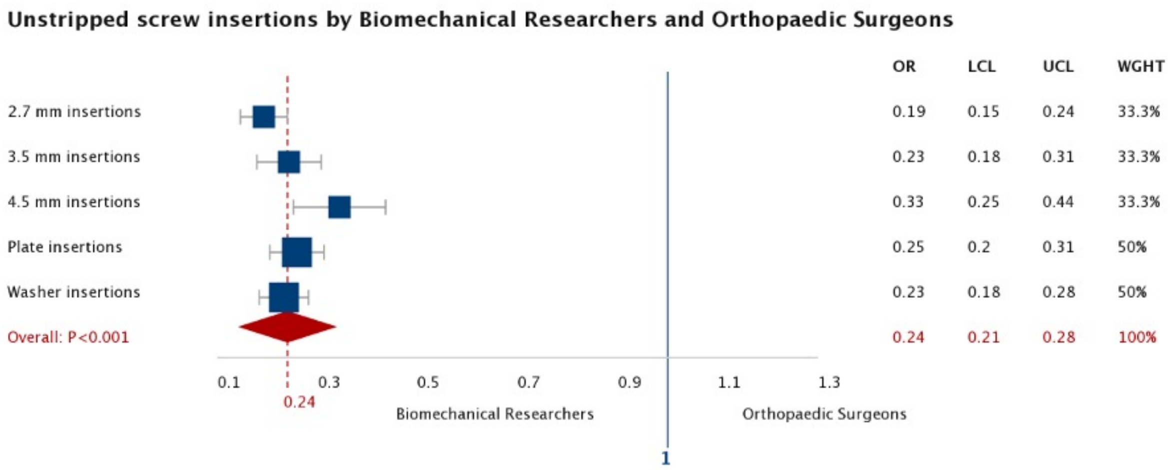

Figure 7-2 - Forest plot of the Odds ratios for surgeons and researchers for unstripped screw insertion (OR- odds Ratio, LCL – lower confidence level, UCL – Upper confidence level, WGHT – weighting).

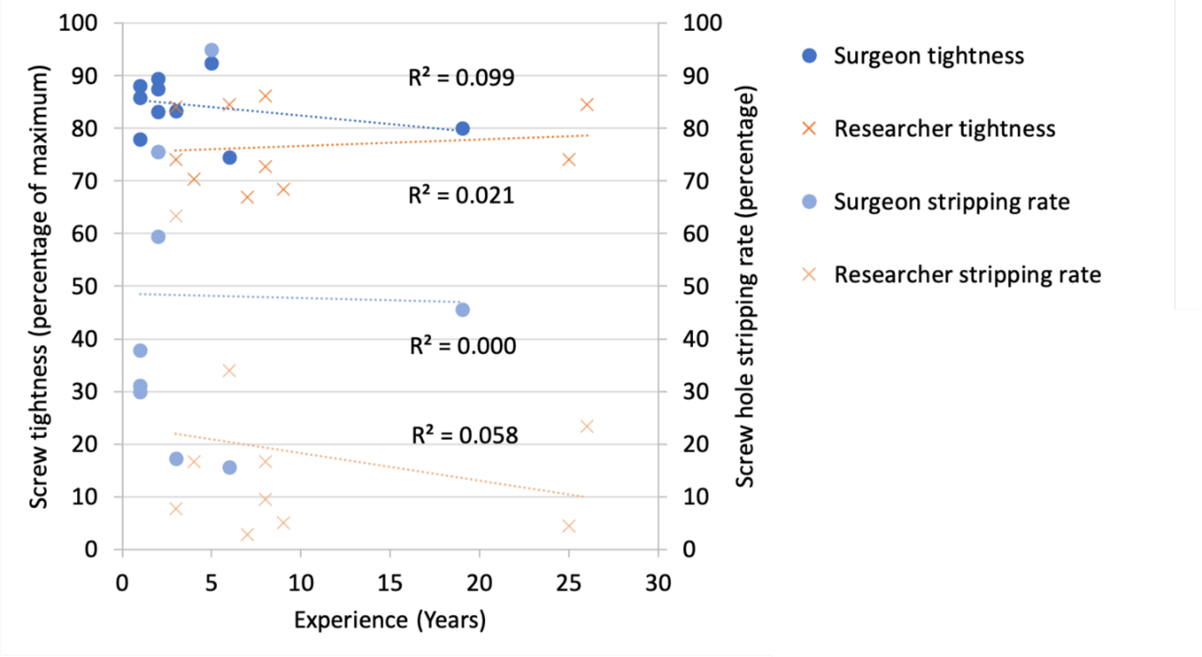

Figure 7-3 - Screw tightness and stripping rates for each participant (10 surgeons and 10 researchers) compared with years of experience, with no significant associations seen.

Both groups showed greater confidence in screw purchase for unstripped insertions compared to stripped insertions: surgeons – 7.4 vs. 6.1 ($p<0.001$), researchers – 7.4 vs. 5.1

(p<0.001) (Figure 7-4).

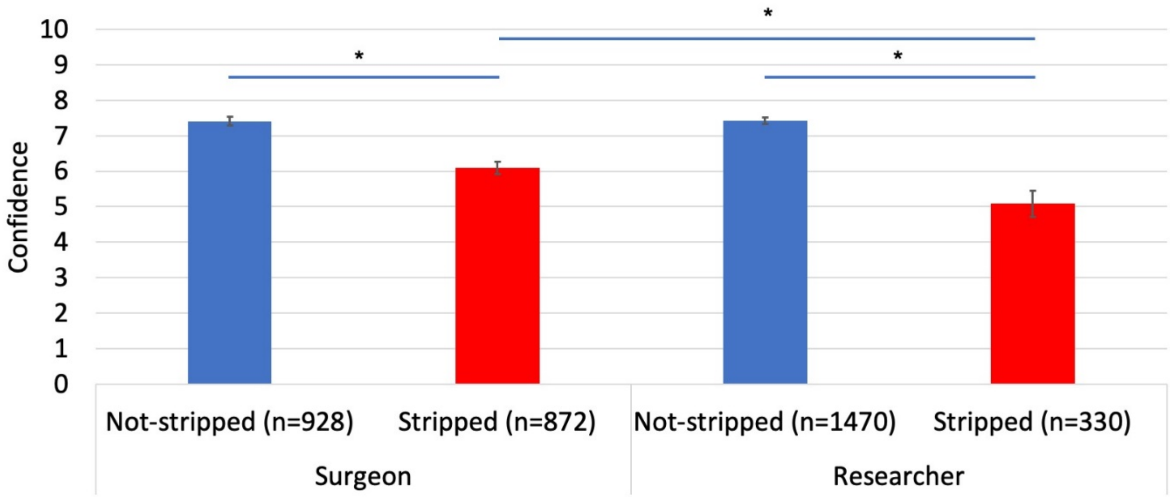

Figure 7-4 - Confidence reported for unstripped and stripped insertions by surgeons and researchers (1 being very poor and 10 being optimal). Significant differences (p<0.001) indicated with asterisk.

Researchers demonstrated a greater ability to correctly predict if a screw hole had been stripped compared to surgeons (p<0.001) (Figure 7-5).

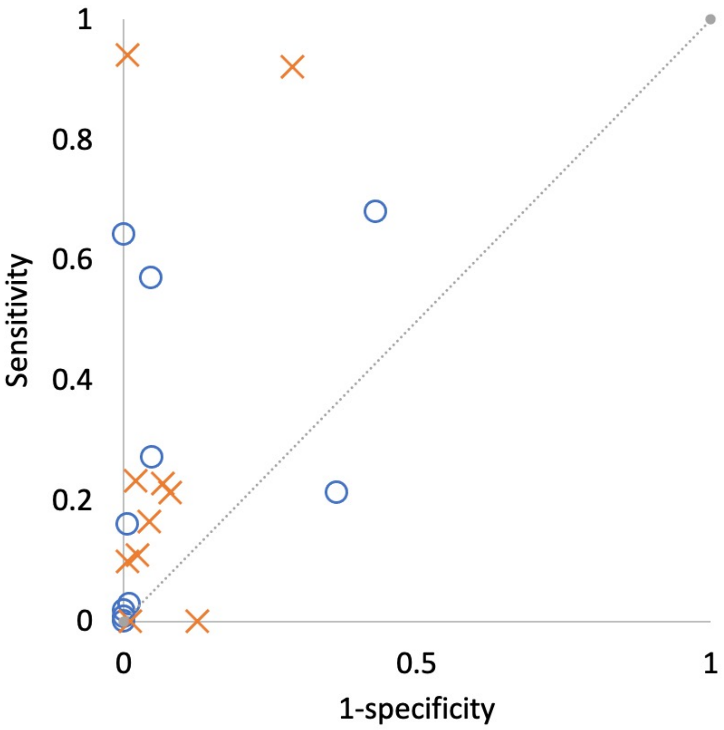

Figure 7-5 - Receiver Operating Characteristic (ROC) curve for the diagnostic ability of surgeons and researchers for screw stripping. Surgeons indicated by blue circles and researchers by orange crosses.

Researchers also performed better overall in identifying good and bad screw insertions, with their assessments of screw insertions being accurate 86% of the time compared to 62% for surgeons.

There was no significant change in screw tightness between the first 10 and last 10 screws inserted for any screw diameter or fixation technique (p=0.058-0.821) (Figure 7-6). A strong correlation was seen in the stripping rate for both the first 10 and the last 10 insertions (R^2=0.890) (Figure 7-7). Using augmented screwdrivers led to a reduction in the stripping rate for surgeons (p=0.162) and researchers (p=0.001)(Table 9).

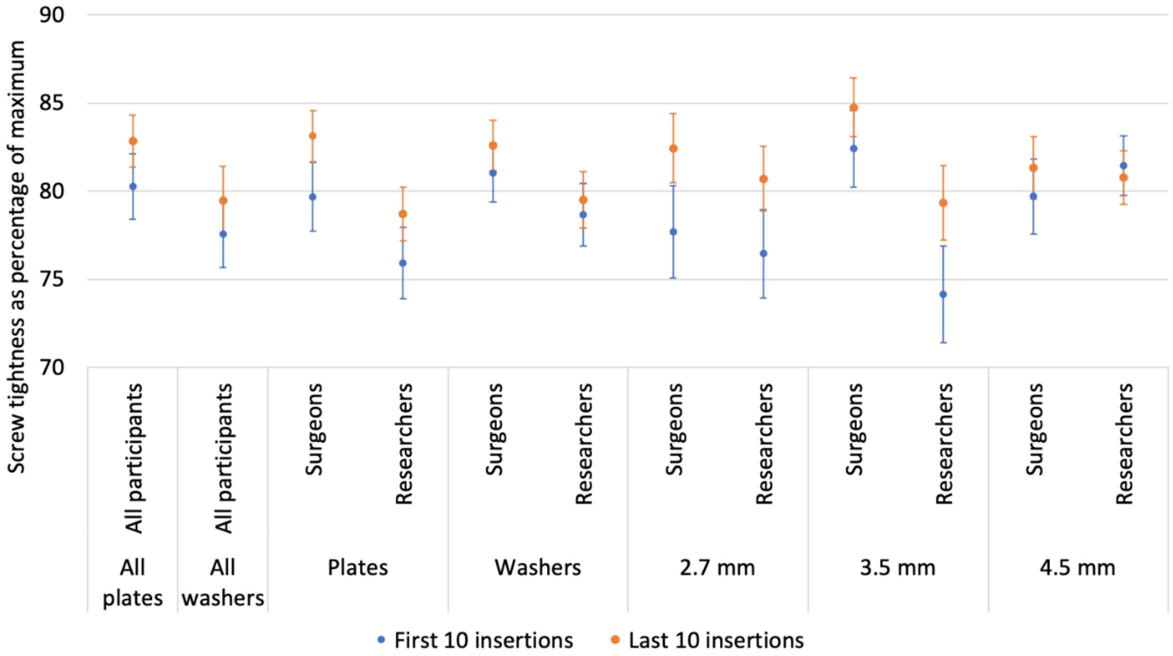

Figure 7-6 - Learning effect – tightness achieved for the first 10 screws against the last 10 screws for surgeons and researchers for each variable.

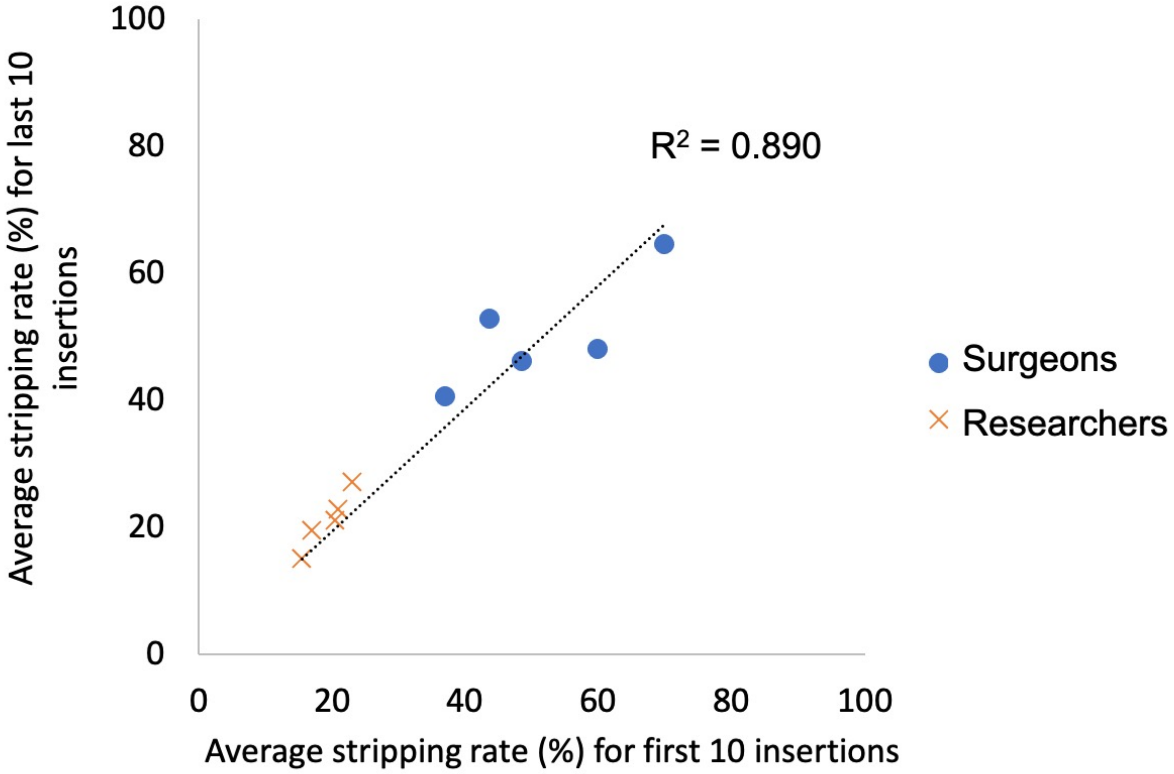

Figure 7-7 - Learning effect – linear regression analysis of the mean average stripping rates for all 10 researchers and for all 10 surgeons, for the first 10 screws against the last 10 screws for each variable (five markers for 1. Plate fixation, 2. Washer fixation, 3. 2.5 mm screw diameter, 4. 3.5 mm screw diameter, and 5. 4.5 mm screw diameter): surgeons shown with blue circles and researchers with orange crosses.

Table 7-2 - Tightness and stripping rates before and with screwdriver augmentation for surgeons and researchers with the 1st, 5th and 10th highest stripping rates.

		Number of attempted insertions	Number of unstripped insertions	Stripping rate (%)	Statistical difference in stripping rate	Unstripped screw tightness (%) (95% CI)	Statistical difference in tightness
Surgeons	Pre-augmentation	90	49	46	P=0.162	77 (73-81)	P=0.036
	Augmentation	90	56	38		83 (79-86)	
Researchers	Pre-augmentation	90	70	22	P=0.001	76 (71-81)	P=0.472
	Augmentation	90	86	4		74 (71-77)	

Discussion

Within this study, surgeons showed a different ability from researchers in controlling screw insertion. There was a spectrum of abilities within both groups, with some surgeons and researchers generating very consistent screw tightness and minimal stripping rates, though both groups had participants who were insensitive to detecting stripping. Our findings raise concerns about the validity of methods using only surgeons in biomechanical research especially when insertion torque is neither recorded nor reported. Studies exclusively involving surgeons may generate more clinically transferable findings by mimicking clinical conditions more accurately. However, the higher rate of stripped insertions that might occur during the experimentation could introduce into the methods an underappreciated confounder given the reduced compression generated and reduced pullout strength of stripped screws (Fletcher et al., 2020e, Fletcher et al., 2019) and their impact on fracture healing (Togni et al., 2011).

This is the first study comparing tightness and stripping rates for different fixation methods and screw diameters. The same stripping rate was seen for both plate and washer fixation with average unstripped tightness close to the optimum tightness, defined as being between 70 and 80% of the stripping torque (Fletcher et al., 2020e, Fletcher et al., 2019). Smaller diameter screws were tightened to a greater percentage of the stripping torque than larger screws, with a greater stripping rate, perhaps as the force required to exceed the stripping torque could be applied more effortlessly. Great awareness of the risks of poor screw insertion appears to be needed when inserting 2.7 mm screw given the high stripping rate seen. Experience did not impact on screw tightness nor stripping rates for either group, potentially highlighting how an individual develops their own technique, that does not significantly change over time. This may occur due to a lack of attention on performance or an inability to critique it, alongside a general trivialisation within the surgical community of screw insertion - that it is easy and does not require special training. This is exemplified with the lack of previous research into surgeon performance(Fletcher et al., 2020d) and the absence of these techniques in surgical curricula. This study highlights the need for improved awareness and training of simple biomechanical procedures, such as tightening a screw without stripping the screw hole.

Good screw fixation is reliant on the ability to contemporaneously critique a screw’s insertion to ensure the screw will perform as intended. If insertion is felt to be poor, alternative remedies, though often suboptimal, can be enacted if the screw hole has been stripped - such as re-siting a screw or inserting a larger diameter screw. Both groups in this study, on average, correctly showed a significant difference in the confidence of a screw’s holding ability between unstripped and stripped screw insertions. However, researchers were appropriately less confident when screw holes were stripped. Building on the need for accurate user assessment, the accuracy in determining when a screw insertion was stripped differed between researchers and surgeons. Accuracy in detecting stripping highlighted another issue with some participants being insensitive to stripping, a finding seen before by Stoesz et al., who found that more than 90% of stripped screw insertions went undetected by surgeons (Stoesz et al., 2014). Additionally, some participants believed a screw to be poorly inserted when in fact it had not stripped the screw hole. Our findings show that proprioceptive assessment appears variable amongst surgeons and researchers, but also that more focus is likely to be needed on training both researchers and surgeons on how to insert screws correctly and what they should be feeling for during insertion.

There was weak evidence of increasing tightness with more insertions, with no change in the stripping rate between the comparative groups of the first third and last third of insertions. This echoes the findings of a larger study into screw insertion variables that showed for all but a few of the tested conditions there was no increase in tightness with more insertions, and that the performance when inserting the first 10 screws was representative of a larger number of screw insertions (Fletcher et al., 2020a). More screws may reflect an individual technique with more accuracy, however using 10 screws to test an insertion condition seems to be sufficient as the tightness does not generally change with more insertions, nor does the stripping rate. These findings can be used to reduce the volume of materials needed in future studies into screw insertion technique.

Awareness of the applied torque value and when optimum torque has been reached was seen to reduce stripping rates. Gustafson et al. investigated surgeons inserting screws into 0.1 g/cm^3 artificial bone models finding a significant ($p<0.001$) reduction in the stripping rate from 42% to 15% when they were unblinded to the applied torque (Gustafson et al., 2016). Bone characteristics and screw geometries can be used to estimate the stripping torque for a screw hole prior to insertion, enabling prediction of an optimum torque that represents 70-80% of the stripping torque (Fletcher et al., 2020e, Fletcher et al., 2019). Using these predictions and augmenting screwdrivers to indicate the torque as it is applied, shows promise for improving osteosynthesis.

One of the key strengths of this study is the number of screws inserted, and thus the power of this study, as this is considerably more than any previous work examining screw insertion outcomes (Fletcher et al., 2020d). The transferability of the findings of our study are greatly enhanced by having 20 individuals each insert 180 screws, and six participants inserting a further 60 screws each (total n=3,960). The similarity between the tightness of the first ten screws inserted and the last 10 screws for a test variable shows that future studies may appropriately investigate a situation with the insertion of only ten screws. However, even ten screws under the same conditions is more than the number used in most previous biomechanical studies into screw fixation (Fletcher et al., 2020d). The apparatus used enabled testing of screw diameters and augmentation in a repeatable fashion, which is especially important given the effects other factors can have; a previous study has shown significant and unpredictable differences in the tightness of screws and stripping rates depending on the conditions screws are inserted under (Fletcher et al., 2020a). Thus, all variables, such as cortical thickness, use of gloves and bone density, were appropriately controlled during experimentation to not introduce confounders.

There were limitations with the study, including that the model used for testing mimicked low density bone, with only unicortical fixation performed which may not be representative of the majority of screw insertions in clinical practice. However, previous work has shown than screw techniques in human cadaveric models mimic those of artificial bone (Fletcher et al., 2020a). Unicortical insertion was used to reduce the amount of artificial bone needed, which will not model most clinical fixations, though bicortical screw fixation has been shown to perform comparably to unicortical fixation; it is the total cortical thickness that effects screw behaviour rather than whether the cortices are split (Lawson and Brems, 2001). Furthermore, the purpose of this study was not to assess a specific clinical scenario, but to have a standardised model to investigate the variations in techniques. Despite the bone density and the stripping torques being low, several participants were able to repeatably insert screws correctly, showing that good fixation for the conditions was possible, and that the poor results seen for some, unfortunately, cannot be explained by the testing arrangement. Finally, no assessment was performed of the strength of the created constructs, though it has been established that with excessive torques, the construct is greatly weakened (Fletcher et al., 2020e, Fletcher et al., 2019, Togni et al., 2011).

The sample of surgeons and researchers analysed frequently showed different screw tightness under the same conditions, with significantly greater rates of screw hole stripping by surgeons. With the majority of screw research being performed by non-surgical, biomechanical researchers, there may be a failure to replicate in vitro findings if the skills of the surgeons differ greater from those making research discoveries. Greater attention to teaching optimal screw insertion to both surgeons and researchers is warranted alongside further investigation into the clinical use of augmented screwdrivers to indicate optimum tightness.

Conflict of interest

The authors have no conflicts of interest relevant to this article.

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7.4 Summary

There is a spectrum of abilities regarding screw insertion amongst biomechanical researchers and orthopaedic surgeons. The clinical transferability of some biomechanical studies might be limited if they do not include surgeons when inserting screws.

These findings mean that there could potentially be variability in research findings depending on who did the experiments, with the same being said for surgery – where all other factors being equal, different surgeons would lead to different outcomes purely due to their manual dexterity and screwing ability. Surgical outcomes could vary purely due to a simple aspect of the surgeon's ability to insert screws.

Augmentation of screwdrivers to make surgeons aware of the torque being applied in real time, greatly improved screw insertion. This was highlighted with the achieved screw tightness being closer to the optimum tightness, alongside reduced stripping rates and increased accuracy in determining if a screw was inserted safely. As stated in other chapters, this highlights the potential benefit to enabling calibration of a surgeon's technique by knowing what different torque values feel like. Also, for some individuals, having training in screw insertion would seem to be very useful – there were some who were stripping the screw holes of most of their insertions, and even then not improving greatly when exposed to augmentation. This may highlight the trivialisation that occurs with regards to exposure to the use of screws and shows the need for basics to be covered early in both the careers of researchers and surgeons.

Chapter 8 - Conclusions and further work

This chapter summarises the findings reported in this thesis and highlights the key aspects with regards to the objectives of this thesis. The further work section describes the next applications of this research in continuing to improve screw fixation.

8.1 Conclusions

The research questions for each chapter of this thesis and their key findings can be summarised as:

1. Surgeons frequently insert screws poorly, reducing screw fixation performance. (Chapter 2)
2. Juvenile bovine bone has been found to be an inexpensive, easy to prepare, readily available model for human bone for biomechanical testing (Chapter 3)
3. Demineralisation methods using hydrochloric acid reliably reduce the model's bone density mimicking that of osteoporosis (Chapter 3)
4. Optimum tightness in both bovine and human cadaveric bone is between 70 and 80% of the stripping torque for that screw hole (Chapters 4 and 5).
5. Tightness for a screw hole can be accurately predicted prior to screw insertion using the screw geometry, bone density, cortical thickness and coefficient of friction between the bone and the screw (Chapters 4 and 5).
6. Several factors related to screw insertion such as bone density, cortical thickness and screw diameter can affect the quality of screw insertion – these need to be controlled for during experimentation and awareness of the variation they may cause is needed in clinical practice (Chapter 6).

7. There is a spectrum of abilities amongst biomechanical researchers and orthopaedic surgeons. The clinical transferability of some biomechanical studies might be limited if they do not include surgeons when inserting screws (Chapter 7).
8. There is a need to enhance surgical training to improve performance, confidence and awareness of problems when inserting screws (Chapter 7).
9. Augmentation of screwdrivers, improves screw insertion, reduces screw stripping rates and increases accuracy in determining if a screw was inserted safely (Chapters 6 and 7).

8.2 Impact, limitations and further work

The findings from this thesis are advancing work in this area in several ways. Firstly, the establishing of juvenile bovine bone as an appropriate model for human bone, and the methods to reduce its density provide other researchers with inexpensive, reliable models to use for their experiments (Ali Akhbar and Yusoff, 2019, Akhbar and Yusoff, 2019, Muñoz et al., 2018, Zhou et al., 2020). The finding of high rates of screw hole stripping amongst surgeons has increased the awareness of this as an issue and is already impacting on surgeons' techniques through dissemination of the thesis results such as changing educational practice at regional and international courses. Translating the thesis findings into clinical practice, pragmatically, surgeons can use measurements of a patient's bone density, or even simply estimate it based on the patient's history and x-rays, and then use this information to calculate how tight to insert screws for different screw holes. Extra care can then be used when inserting screws to ensure that the correct tightness is applied, or pre-existing tightness-limiting screwdrivers can be used to control insertion.

Surgical education is changing, to include screw insertion performance given how this has previously been overlooked. Augmentation of screwdrivers can be used to teach surgeons how tight they are inserting screws and enable them to develop greater proprioceptive awareness of what torque they are applying when inserting screws. Finally, in the coming years the hope is to develop the screwdriver needed to improve screw insertion, by collaborating with existing designers of drills to link the findings from this thesis to create a surgical aid to show correct tightness. As a surgical aid designed to help surgeons and not implanted into the patient, the time to take the designs from the laboratory to the operating table time is greatly shortened compared to the journey for new implants. By developing integrated drills and screwdrivers that can communicate with each other, it will not only make screw insertion safer, but operations faster – this provides financial benefits alongside reducing risks for patients with shorter anaesthetics. Measuring outcomes in fracture fixation can be difficult given the multiple factors involved in fracture healing and management. However, given the fundamental aspect that appropriate and well performed screw fixation plays in the journey of fracture management, general health quality outcome measures could act as a surrogate for improved fixation given the pleiotropic benefits that might be seen, such as faster healing and earlier weight bearing. The importance of weight bearing is becoming increasingly understood in the management of lower limb injuries (Richardson et al., 2022). Earlier weight bearing and mobilisation will improve loading of the bone and in turn should aid healing. This will have multiple benefits not limited to earlier discharge and return to function. Surgeons might be reducing the weight bearing instructions to patients due to concerns about the stability and strength of their construct, concerns that might be mitigated if the constructs had screws that had be knowingly optimally inserted. In parallel to this, if the optimum screw insertion could be performed, for example by using augmentation intraoperatively, then the number of screws needed for a fracture could be reduced, leading to cheaper, faster surgery that might require smaller incisions as smaller fixation constructs would be needed. Small surgical ‘footprints’ mean less morbidity to a patient and could be expected to enhance their recovery.

In summary, this thesis has characterised an important, common and previously underappreciated issue in orthopaedic surgery, and identified ways to address this and optimise screw insertion for fracture fixation.

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